Patenting Life Forms in Europe

PROCEEDINGS

An International Conference at the European Parliament

7-8 February 1989

Co-organised by the International Coalition for Development Action and the Green Alternative European Link in the European Parliament.

A publication of ICDA Seeds Campaign

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**This report is dedicated to Thies Julius,
born just a few days before the conference.**

**Your children are not your children,
they are the sons and daughters
of Life's longing for itself.
They come through you
but not from you.
And though they are with you
yet they belong not to you.**

(Kahlil Gibran: The Prophet)

INTRODUCTION

This report presents the proceedings of a first major public debate at the European level on the implications of extending industrial patent protection to so-called inventions of biotechnology. This International Conference on *Patenting Life Forms in Europe* drew some 200 people, including the press, to the European Parliament in Brussels on 7-8 February 1989. The event was co-organised by the International Coalition for Development Action (ICDA) and the Green Alternative European Link in the European Parliament (GRAEL).

Why such a conference? For two reasons. First of all, the EEC is about to take decision on a draft Directive which would make virtually all forms of life subject to exclusive monopoly control in all EEC memberstates. This Directive, *The Legal Protection of Biotechnological Inventions*, reproduced in Annex 1, was elaborated by the Commission's Directorate General for Industrial Affairs (DG-III) without a broad consultation process among the groups that will be most affected by the patenting of life. Given the vast ethical and socio-economic implications of the proposal, the organisers felt that it was imperative to offer a platform to European citizens to voice their opinions and concerns about the patenting of life.

Secondly, it appeared urgent to inform and mobilise the general public on this issue before the national governments and European Parliament take a position. A major aim of the conference was to assemble some serious food for thought for those elected to voice the concerns of European citizens on this most serious affair. This report, then, is strongly directed to the attention of our governments, MPs and MEPs. In fact, several speakers at the Conference closed their interventions with direct and explicit appeals to our representatives at the national and EC level.

While focusing on DG-III's proposed Directive, at the heart of our two-day discussion was the question whether or not life should be patented. As several speakers stressed, the patenting of life will have tremendous implications for all of us. Perhaps amongst those who will be most directly affected is the European agricultural community. It is the farmers and the plant and animal breeders who will most strongly feel the impact of the privatisation of the very building blocks of life.

For this reason and others, we would like to express here our sincere regrets that the representative of the Commission's DG-VI (Agriculture) did not take the place reserved for him at the podium to address this question precisely. It is well known that DG-VI is drafting a regulation on Community Breeders' Rights which in its present form completely clashes with the provisions of DG-III's Patenting Directive. In trying to promote a democratic and open exchange of information and views, the conference organisers hoped that such a fundamental and important point for farmers and breeders alike would be clarified at this public meeting by DG-VI. This was, regretably, not to be the case.

In these proceedings we have essentially reproduced the written papers that were provided to us by the Conference speakers. In those cases where papers were in French or German, we translated them. For some interventions, no or only summarised papers were provided. In these cases we took material from the tape recordings of the conference. Although hardly any editing was done, ICDA assumes full responsibility for the presentation of the speakers' interventions and papers in these proceedings.

Finally, we would like to express our deepest thanks to the following organisations for making this Conference financially possible: Evangelische Kirche in Deutschland (FRG), GRAEL (EUR), Gruppo Parlamentari Verdi (I) and Union Européenne pour la Protection des Animaux (EUR).

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Renée Vellvé,
ICDA SEEDS CAMPAIGN

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ABBREVIATIONS

ASSINSEL	International Association of Plant Breeders for the Protection of Plant Varieties
BST	bovine somatotropine (bovine growth hormone)
CAP	Common Agricultural Policy
CEE	Communauté Economique Européenne
CGIAR	Consultative Group on International Agricultural Research
CIMMYT	Centro Internacional de Mejoramiento de Maiz y Trigo
CNRS	Centre National de la Recherche Scientifique
COGECA	Comité Général de la Cooperation Agricole de la CEE
COMASSO	Association of Plant Breeders of the EEC
COPA	Comité des Organisations Professionnelles Agricoles de la CEE
DG-III	Directorate General III (Internal Market and Industrial Affairs)
DG-VI	Directorate General VI (Agriculture)
DNA	desoxyribonucleic acid
EEC	European Economic Communities
EPC	European Patent Convention
EPO	European Patent Office
FAO	Food and Agriculture Organisation (UN)
FINRRAGE	Feminist International Network of Resistance to Reproductive and Genetic Engineering
GAB	Gruppo di Attenzione sulle Biotechnologie
GATT	General Agreement on Tariffs and Trade
GRAEL	Green Alternative European Link in the European Parliament
IARCs	International Agricultural Research Centres
IBPGR	International Board for Plant Genetic Resources
ICC	International Chamber of Commerce
ICDA	International Coalition for Development Action
INRA	Institut National de la Recherche Agronomique
IOCU	International Organisation of Consumers Unions
IRRI	International Rice Research Institute
KGB	Kontact Groep Biotechnologie
MEP	Member of European Parliament
MIT	Massachusetts Institute of Technology
NARs	National Agricultural Research institutes
NGOs	Non-Governmental Organisations
OECD	Organisation for Economic Cooperation and Development
PBR	Plant Breeders' Rights
RAFI	Rural Advancement Fund International
RFLP	restriction fragment length polymorphism
RNA	ribonucelic acid
SADCC	South African Development Cooperation Conference
TNCs	transnational corporations
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNESCO	United Nations Education, Science and Culture Organisation
UPOV	Union for the Protection of New Varieties of Plants
WCC	World Council of Churches
WHO	World Health Organisation (UN)
WIPO	World Intellectual Property Organisation (UN)

PATENTS IN BIOTECHNOLOGY: THE LEGAL BACKGROUND

R. Stephen Crespi

Original: English

Introduction

This presentation is a brief overview of the patent system under a series of headings.

The nature of patents

A patent is a property right granted by the State Authority which excludes other from the use of the patented invention without the consent of the patentee. An invention without a patent is not necessarily a property right. However, a patent does not confer a positive right to use an invention because freedom of use may be dependent on prior rights.

The patent application

To obtain a patent, an application must be filed with the relevant national authority (Patent Office) and will be examined for compliance with legal requirements. After a process of negotiation between the applicant and the Patent Office Examiner, the application will be accepted or rejected. This examination is principally concerned with the written specification of the invention which must be filed with the application and which must define the scope of the protection sought.

Territorial extent

Separate patent applications are usually necessary in each country where protection is required but a single application in the European Patent Office can cover 13 European countries up to the point where rights are granted. An international application under the Patent Cooperation Treaty can cover up to 40 countries, but only through the initial stages of procedure. There are no such things as world patents.

Patentability

Among the principal requirements for patentability there are four basic requirements, three of which the invention itself must fulfill, namely, it must have (1.) novelty, (2.) inventiveness and (3.) practical utility or industrial applicability while the other (4.) concerns the specification; this must be adequate in content to enable those of ordinary skill and experience in the field to follow the directions and obtain the promised results. The invention is defined in the claims which form part of the specification. Common forms of claims are directed to an *apparatus* or *device*, a *process* or *product* of manufacture, and a *method* of treatment, testing or use.

Official examination

The Patent Office will carry out a search of previously published documents including the scientific and patent literature to determine the relevant prior art. Following this the application will be examined in the light of the search results. This usually involves argument about the specification, especially the scope of the claims, and may take considerable time to settle.

Opposition or re-examination

Even after acceptance by the Patent Office, a patent application or patent can in most countries be opposed by third parties who may raise objections and prior art similar to or additional to those already overcome by the applicant. This is usually termed Opposition and involves argument between the applicant/patentee and Opponent, who have equal status as contending parties. U.S. patent law does not provide for opposition in this sense, but allows a third party to request official Re-examination of the patent in the light of prior art.

Duration of the patent

The term of a patent differs from country to country. In most European countries the term is 20 years from the *application* date. In the U.S.A. and Canada, a patent last 17 years from *grant*. The payment of annual renewal fees is required in most countries to avoid lapsing of the protection.

The function of patents

The primary function of a patent is to define the rights to which an inventor is entitled for his invention. The inventor must disclose information about his invention, rather than keep it a secret, so that his entitlement may be determined. Hence arises the so-called bargain theory according to which rights are given in return for full disclosure of an invention which may then be used freely by the public when the term of protection has expired. As research has become more costly, requiring significant financial investment, stress has been laid on the concept of a patent as a reward for undertaking the risk of such research which may not always achieve useful results. Nowadays the restrictive character of patents, though legally quite proper, is less emphasised, especially as patents are used more and more to provide a vehicle for technology transfer through the grant of licenses by the patentee.

A patent seeks to control the exploitation of a *particular* invention which has been generated in order to solve a technical problem, but it can be legitimately avoided by the de-

vising of different and alternative solutions to that same problem. Thus, designing around a patent is a common feature of competitive enterprise. From this aspect, a patent can be viewed as a stimulant to competition.

Life-forms are legitimate objects of industrial research and are therefore proper subjects for patent protection

Patents in biotechnology

Historically, the patent system came to birth to meet industrial needs. Industry was perceived as activities carried on inside factories typical of the first Industrial Revolution. Manufacture was the key word. Agriculture, at least as regards processes and products, was felt to be outside the realm of patent law. Living things were also assumed to be excluded as being products of nature rather than products of manufacture. This restricted view no longer persists in most industrialised countries. Thus the European Patent Convention of 1973 (EPC) declares Agriculture to be a kind of industry. Nevertheless, vestiges of the older idea can still be found. For example, there is a specific EPC exclusion from patentability as regards the so-called essentially biological process (Article 53(b)).

The German Supreme Court was the first to point the way to a new attitude toward biological inventions in the famous Red Dove case of 1969 and the Baker's Yeast case of 1975 in which the patentability of living things was confirmed in principle. The most significant breakthrough in this respect, however, was the decision of the United States Supreme Court in 1980 to allow a patent for a genetically manipulated micro-organism (Chakrabarty). Although these cases were decided on legal grounds, it is hard to believe that no other considerations entered into the mind of the courts. From the point of view of industrial and social policy, the application of technology to living organisms as industrial tools or products should raise no objection in principle. Considered as economically useful entities, life-forms are legitimate objects of industrial research and activity and are therefore proper subjects for patent protection as regards both the products themselves and processes for their production.

Classical biotechnology

After the Second World War, the expansion in the use of fermentation technology by the pharmaceutical industry to produce antibiotics, amino acids, enzymes and other secondary metabolites established the need for legal recognition of micro-biological processes and products as important objects of patent protection. However, even now there are no patent statutes or treaties specific for life forms and consequently the patentability of these items must be decided according to the general patent law. The requirement for the biological inventor to provide an adequate description of such a complex thing as even the simplest of micro-organisms has caused the Patent Offices and courts of many countries to develop special rules of procedure by official regulation or by case law. On an international scale, the Budapest Treaty of 1977 regulates the procedure for depositing novel biological material in official Culture Collections as depositories from which samples may eventually be made available to the public in accordance with patent procedure.

Modern biotechnology

From its beginnings in classical biotechnology, our scientific understanding of the hereditary process and of the nature of genetic material has given rise to the modern techniques of recombinant DNA and cell fusion. These methods

There are no such things as world patents

considerably extend the possibilities of classical microbiology and enable new micro-organisms and higher life-forms to be tailored by biological scientists. Insofar as these new creations have industrial utility, the industries that make use of them insist that these products should also be patentable for the same fundamental reasons that apply to inventions in other technologies. So long as inventors can comply with the legal conditions of novelty, inventive step, practical utility, and the provision of an enabling disclosure, there should be no discrimination against the protection of these inventions under patent law.

In the area of plant biotechnology the present draft Directive does not live up to the promise it shows in other directions

The competitive climate

The United States and Japanese patent laws are commonly considered to provide the strong protection which stimulates innovation in this field. These foreign laws do not suffer from the specific statutory exclusions from patentability such as exist under European law, e.g. Article 53(b) of the EPC which excludes plant and animal varieties and related process technology from patent protection. The favourable climate in the home market in these countries may explain the innovative success of their industries. The European inventor feels himself to be under a disadvantage because of the comparative restrictiveness of his domestic law. The huge public investment in research as well as that of private industry calls for a re-examination of European law to create parity of treatment, and of the conditions under which our inventors work.

Regulating the system

It must always be remembered that inventors are not allowed the protection of even limited monopolies without rigorous examination and without just cause. Under the strict official examination procedure carried out by our European and National Patent Offices, the extent of the protection granted by a patent must be proportionate to the technological contribution of the inventor. After this there is yet a further stage in which competitors and other third parties can take up an adversarial role. These two factors combine to ensure that the scope of protection granted is reasonable. Patent laws and other laws in Europe and in many other countries also have provisions for preventing the abuse of monopoly: these provide adequate safeguards without resorting to other manoeuvres designed to water down the protection for biological inventions.

Designing around patents is a common feature of competitive enterprise

Conclusion

The proposed EEC Commission Directive on Biotechnological Inventions is a step forward to the creation of a climate in which past prejudices against patents in the field of biology are to be removed. In the area of plant biotechnology, however, the present Draft does not live up to the promise it shows in other directions. The plant patent issue must be thoroughly understood so that unjustified fears may be dispelled. There are hopeful signs that the two sides to this question may at last come together to begin to open the dialogue without which no progress can be made.

THE PROPOSED DIRECTIVE ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Sandra Keegan

Original: English

Introduction

I have been invited to speak to you today about the proposed Directive on the legal protection of biotechnological inventions. As the conference organisers noted in their invitation, *There is quite evidently a tremendous lack of understanding, not to mention confusion, and even fear, about what 'patenting life forms' really means in European society today.*

I am a lawyer who was involved in the drafting of the Commission proposal. However, most participants are not lawyers and will therefore be more particularly interested in the major features of the proposal and less interested in historical details of treaty language now relevant to patenting inventions concerning plants and animals.

I shall first describe in general terms what the proposal for a Directive can achieve and shall compare this with the situation which could arise in the absence of a Directive. In doing so, I will need to refer, usually in general terms, but occasionally in details, to aspects of the European patent system, a system which is composed of two interrelated sets of patent law. Finally, and particularly in view of the purpose of this present conference, I will address some of the typical ethical arguments commonly raised against the patenting of transgenic animals.

It should be understood that all views expressed here today are wholly my own and cannot in any way be attributed to the Commission of the European Communities or the Directorate General for the Internal Market and Industrial Affairs.

As my last introductory remark, let me lay to rest a myth: the suggestion that we plan to patent human life. It is largely an artificial issue, but since the notion has been raised in connection with the proposed Directive, I would like to dispose of it. As far as the Directive is concerned, it was never and is not now intended to suggest that claims in a patent application to human beings could be regarded as patentable subject matter. The notion that inventions relating to human are unpatentable —with limited exceptions— is one which is deeply ingrained in patent laws throughout the world. The Commission has never contemplated changing this principle. It can be stated in legal terms as: claims for genetically engineered humans are not to be regarded as patentable subject matter.

That is all I intend to say about patenting of humans. I would now like to turn to what the patent system protects and what it does for an inventor.

What does a patent do?

The patent system in every country in the world that has one is meant to reward the creative effort of someone who has invented something deemed useful to society. The reward consists of a set of exclusive rights for a limited period of time. In exchange for the public disclosure of his invention, a patentee acquires the following rights:

The right to prevent those who do *not* have his consent:
— from making, offering, putting on the market or using a patented *product*;
— from *using a process* which is the subject matter of the patent; and
— from offering, putting on the market, using, or importing or stocking for these purposes a *product* obtained *directly by a patented process*[1].

So these are the *exclusive rights* acquired by an inventor of a product or a process who obtains a patent for his invention.

Let me lay to rest a myth: the suggestion that we plan to patent human life

How are patents obtained?

Patents in Europe may be granted in two ways:
— by a national patent office for the country in question, or
— by the European Patent Office for one or more countries party to the European Patent Convention.

Confusingly, the countries party to the European Patent Convention (EPC) are not the same as the Members of the European Communities. Most EEC Member States (but not Denmark, Ireland and Portugal) are party to the EPC but several non-Community States are also party.

Under the European Patent Convention, the contracting States[2] have undertaken to grant patents for any inventions which are susceptible of industrial application, which are new and which involve an inventive step[3].

These are referred to in the plural, in a kind of shorthand, as the criteria for patentability and, except for Ireland and Portugal (until 1992), are the same for national or European granted patents.

It is worth noting for our purposes that the EPC article defining industrial applicability states: *An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.*[4] The EPC does not define agriculture, but the Concise Oxford Dictionary states that it is the science or practice of cultivating the soil and rearing animals. Therefore the drafters of the European Patent Convention clearly intended to provide that inventions in the field of agriculture could be patented, if they fulfill the criteria of patentability. There is no question about this.

The drafters of the EPC clearly intended to provide that inventions in the field of agriculture could be patented

As an example of what might be considered to be patentable in practice by the European Patent Office, let us examine some relevant provisions of the Guidelines for Examination of the EPO. There, we find, for example, that methods for the treatment of sheep to improve growth or to improve the quality of the flesh, or to increase the yield of wool, are indicated as patentable[5]. In short, inventions pertaining to animals are regarded as patentable.

Let us now turn to the Directive and to how some of these legal principles have been translated into concrete propositions.

What does the Directive do?

The Directive is intended to answer many of the legal questions which are raised uniquely by inventions in biotechnology such as:

Can a patent be granted on a living organism?
Answer: Yes.

How far does the patent law concept of discovery exclude preexisting natural material from patentability?
Answer: Mere discoveries are not patentable but natural material can be patentable if sufficient human intervention has taken place, for example, in identifying, isolating and purifying natural material.

How far do patent rights extend in patented but self-replicable inventions such as patented microorganisms?
Answer: In all subsequent generations for the life of the patent.

What is the result in patent law of the exclusion of plant and animal varieties from patentability?
Answer: Plants and animals are patentable if the criteria for patentability are fulfilled.

Can the mechanism of depositing a microorganism or other self-replicable material fulfill the patent law requirement of a repeatable disclosure of the invention?
Answer: Yes. Likewise a patent granted on the basis of a deposited sample of material would not be declared invalid in subsequent patent litigation for lack of sufficient disclosure.

The Directive assumes that no reason exists to deprive an inventor in the field of biotechnology from the benefits and obligations of the patent system if his invention fulfills the criteria for patentability. Some inventions, whether or not they fulfill the criteria for patentability, are excluded from patenting. This brings us to the question of whether inventions relating to plants and animals are patentable.

Exclusions

Patents are granted for inventions -- creations of something new and inventive and industrially applicable. When evaluated by the standards of patent law, innovations by plant breeders usually fail to obtain protection. A recognition of this phenomenon resulted in the creation of the Plant Breeders' Rights in America in the 1930s, and in Europe in the 1960s. The EPC[6] and the national patent laws of most Member States contain explicit exclusions from patentability of plant and animal varieties and essentially biological processes for the production of plants and animals. These exclusion were adopted for two reasons:

1) it was generally assumed that plant varieties could not fulfill the criteria for patentability, based on experience with German patent law prior to 1960; and
2) to avoid protection by both patents and Plant Breeders' Rights of plant varieties.

Although no system for the protection of animal breeding has been set up, animal varieties seem to have been excluded from patent protection without any serious thought to a possible need for the protection of animals by either type of system.

The tailor-made system for protecting plant varieties was thought perhaps to remove plants from patent protection

As a result of these provisions, in the 70s and 80s, it was not clear whether patents could be granted to plants and animals resulting from biotechnological processes, even though the criteria for patentability were fulfilled. This was because the tailor-made system for protecting plant varieties was thought perhaps to remove plants from patent protection. At a minimum, it was intended to avoid double protection by patent and Plant Breeders' Rights of the same plant variety. Beginning in 1983, the services of the Commission began to seriously examine the possibility of a Community initiative.

Legal precedents to the Directive

Looking at past cases, the Commission found that the question of whether biology and biological forces could be considered patentable was considered by the Supreme Court of the Federal Republic of Germany in 1969. In a case relating to a method of breeding a red-coloured dove, the Court held that the methodical use of biological forces can have the requisite technological nature for patent law purposes to be considered patentable subject matter[7]. So before the development of modern biotechnology, it was explicitly recognised by the Supreme Court of at least one Member State that inventions relating to living matter, and in particular animals, could be regarded as patentable.

A little more than ten years later, the European Patent Office was asked to grant a patent to propagating material for certain genera of plants relating to a process for chemical treatment. The Office decided to grant the claim notwithstanding the exclusion of plant varieties under European patent law[8]. Thus, the general consensus was that living matter could be patented, but no one was quite sure to what extent. This was the general background when the Commission was developing its position on how to improve the legal environment for biotechnological inventions.

While the Commission was finalising its draft proposal, the EPO decided to grant the claims to a biotechnological process for creating new plants and allowed the claims for the plants produced by this process as well[9]. Since the adoption of the proposal by the Commission last October, the examining division of the EPO in Munich decided not to grant the claims to a genetically engineered mouse developed by Harvard University researchers which is the subject of a patent granted last year by the US Patent and Trademark Office. This decision is under appeal. The Directive proposes, as mentioned earlier, that animals should be patentable.

The Directive will also ensure, however, that other inventions will be patentable, such as

— a genetically engineered bacterium which eats and then degrades crude oil which has spilled into the ocean or residual oil remaining in an oil tanker which otherwise would be removed by pumping it into the ocean; or
— a plant which, when eaten by insects, produces a toxin which then kills the insect, making the plant insect resistant without pesticides.

What if there were no Directive?

The Directive lays out a set of principles for use with all twelve national patent laws. This will result in a broadly parallel approach in each national patent system. As is true for all proposals included in the White Paper on the Completion of the Internal Market, the intent is to achieve a situation where differences in laws and practices which would negatively affect the establishment of the internal market have been minimised.

The Commission had as a starting point the legal precedents which we referred to earlier. The question of whether inventions relating to animal breeding could be the subject of a patent had already been answered in the affirmative by the Supreme Court of one Member State.

The question of whether plants and plant material such as seeds could be protected by patents had also been answered in the affirmative by the European Patent Office. The inference to be drawn was that the exclusion of varieties from patentability did not result in the exclusion of all plant material and all plant classifications, other than varieties.

As a point of departure, the Commission studied the Guidelines for Examination of the EPO, the implementing rules of the EPO and their patent grant practice in individual cases. Then, taking advantage of the years of work by the Committee of Experts for Biotechnological Inventions of the World Intellectual Property Organisation which had already addressed exactly the same problems as those confronting the Commission, the services of the Commission produced a text for a proposed Directive developed from all these sources.

It is therefore not an exaggeration to say that, on the basis of existing patent law and jurisprudence, a national patent system could come to the same conclusions and legal results as those proposed in the Directive. Without the Directive, however, it is virtually certain that no consistent approach could emerge in all twelve Member States of the Community.

Moreover, the patenting of an invention which is itself alive or makes use of living material is not a new idea. In 1873, Louis Pasteur obtained a patent on a specially developed yeast strain for the production of pasteurised milk. So we can see that the Commission's proposal is based on ideas and principles which have formed part of patent law for some time. Experience seems to suggest a past lack of ability on the part of inventors to fulfill the criteria for patentability, rather than a legal impediment in the law itself for the grant of patents for inventions relating to living matter.

A national patent system could come to the same conclusions as those proposed in the Directive

Ethics, morals and patenting?

Perhaps you are saying, That is all fine and well for yeast strains and for plants, but what about patent protection for higher organisms? What about patents on cows and pigs? Doesn't this raise ethical and moral questions? Let us examine some of the ethical and moral arguments against the patenting of animals[10].

Arguments of an ethical or moral nature raised against patenting involve drawing conclusions about man's relationship to the world and making distinctions between the li-

ving and non-living. For example, the fear has been expressed that, in reducing living matter to a mere description, we have deprived a living organism of its special status as living. This in consequence removes the respect which we should have for living organisms. Putting it differently, in our pursuit of innovation, maybe we may become unwitting advocates of a purely materialistic view of life.

Man is unique in his ability verbally to describe the natural world. To assert that reducing an invention of living matter to a written description implies that we, as a society, ascribe identical values to non-living matter as to living matter is unfounded. An invention concerning living matter, such as a cancer-prone mouse or a strain of yeast, can be described —and must be described— and regarded as a new product for patent law purposes, but this does not render it devoid of other characteristics or strip it of values which society as a whole ascribes to such living matter.

Just because material is of human origin does not necessarily mean that it has a particularly strong moral significance

What about the introduction of human genetic material into animals? As an example, the introduction of human genetic material for growth into farm animals produces greater animal growth. Does this have implications of an ethical or moral nature?

Implicit in the suggestion that this raises ethical and moral concerns is the notion that human material, human tissue is different in some moral or ethical way from other material. Although this may be true to a certain extent, it would appear to exaggerate the moral feeling associated with human genetic material relative to other human material. There is little or no association of the sanctity of human life with human parts *as such*. Just because material is of human origin does not necessarily mean that it has a particularly strong moral significance.

What about animal rights? Do we as a society feel that, like humans, animals cannot be confined or killed unless an overriding interest in the good of society so demands? We do not. Since we allow animals to be bred, kept in captivity and/or killed for pets, food and clothing, we as a society clearly do not subscribe to a principle of the sanctity of animals similar to that we associate with humans. Moreover, by such actions, we demonstrate that society is willing to treat animals as the means to human ends.

Other arguments relate to man's relationship with and responsibility for the world around him. This argument suggests that mankind is expected to take proper care of the earth's resources and environment in the sense of preserving creation. The notion of mankind as caretaker of the earth has developed relatively recently. The static view of nature reflected in the caretaker role for mankind belies the fact that over the course of the history of earth, in which man is only a recent phenomenon, thousands of species have come and gone. Evolution has played its role in the continuing development of the natural environment. What exists on earth at present bears no resemblance to that which occupied this space millions of years ago. In natural extinctions, species are replaced and diversity is retained.

In the late twentieth century, it has become accepted that we cannot overexploit our natural resources simply to maximise current benefits. While we may recognise that natural extinctions follow natural laws, we now believe that we should exercise care in the management of our natural resources to avoid unnecessary damage to the environment and unnecessary loss of environmental quality and genetic diversity. Nothing in the patent system itself threatens these values. Moreover, there has been a far greater loss of genetic diversity from intensive farming methods over the past half century than at any other time in man's history.

Further questions may be posed: Will the patenting of animals lead to greater animal suffering for the reason that the outcome cannot be predicted? Does patenting reflect an inappropriate sense of human control over animal life and an underestimation of the value of non-human life? Is the patenting of animals the first step toward a decline in the belief in the sanctity and dignity of life?

Beginning only recently, our society has accepted the idea that animal suffering has a moral aspect and should be avoided. Some, but not all, animal research is subject to regulation so as to avoid duplicative and unnecessary suffering. Generally, however, we still regard human interests as taking precedence over animal interests.

Patenting animals will encourage research with animals. In this connection, we should re-examine whether greater rigour should be instilled in the current rules on animal research, not whether we should preclude patenting so as to avoid encouraging animal research. Likewise we should recognise that, while we can enjoy the benefits of biotechnology and simultaneously protect animals from inappropriate suffering, a genuine moral problem needs to be addressed in the form of ensuring that the rules on animal research take account of our societal concerns to avoid unnecessary suffering.

Moral arguments against the patenting of animals have thus far failed

Some recent development in biotechnology have actually improved our ability to cure animal disease, improve animal health and reduce animal suffering: for example, current field trials of rabies vaccines for foxes; reduction of the use of test animals by developing better monitoring methods for animals used in pharmacological or toxicological testing; the ability to use lower species for laboratory testing relevant to higher species (especially man), such as is exemplified by the Harvard University cancer-prone mouse; and the development of *in vitro* test methods.

Ethical concerns relating to an inappropriate control over non-human life, an underestimation of the value of non-human life and the decline in the belief of the sanctity and

dignity of life raise moral claims for animals which most people are not prepared to accept. The most that our society seems prepared to accept for animal rights is the right not to be forced to suffer unnecessarily. There is no inherent notion of the sanctity of animal life as such, given that we slaughter millions of animals for food every year.

It is clear that we view human life and animal life differently and that we ascribe different values as a society to these beings. The suggestion that if we, as a society, patent animals that we have thereby begun to devalue the sanctity and dignity of human life is without foundation. Nor do we, by patenting animals, pave the way for genetic engineering and patenting of humans, thus diminishing the value of the sanctity of life. We do not yet concur on the proposition that animals and humans are of equal dignity and value, nor are we likely to do so.

Moral arguments in favour of patenting seem persuasive

What conclusion should we draw from our analysis of the claims made by the animal rights movement? We should, I believe, conclude that none of the arguments at present put forward to preclude patenting genetically engineered animals should lead us to opposing patenting.

Do any moral arguments exist in favour of patenting of transgenic animals? Yes, two strong moral arguments exist. First, that the patent system encourages worthwhile results because it provides an incentive to create useful inventions; and secondly, that inventors are *entitled* to patent rights as the fruits of their intellectual labour in the creation of a useful invention.

Moral arguments against the patenting of animals have thus far failed while moral arguments in favour of patenting seem persuasive. Those who oppose the patenting of transgenic animals should either use other than moral arguments to convince us of their opposition or should provide us with reasons to support their view of our need to revise our entire relationship with the non-human living world. Perhaps some of the other speakers will provide us with such arguments and reasons.

NOTES:

(1) *Community Patent Convention*, Article 29.

(2) Austria, Belgium, Federal Republic of Germany, France, Greece, Italy, Liechtenstein, Luxembourg, the Netherlands, Spain, Sweden, Switzerland and the United Kingdom.

(3) *European Patent Convention (EPC)*, Article 52.

(4) *EPC*, Article 57.

(5) Part C, Point 4.3.

(6) *EPC*, Article 53(b).

(7) *Rote Taube* Decision of 27 March 1969, Federal Supreme Court, Federal Republic of Germany, 1 IIC 136 (1970).

(8) *Propagating Material - Ciba-Geigy* Decision of the Technical Board of Appeal 3.3.1 dated 26 July 1983, Decision T49/83, OJ EPO 1984, p. 112.

(9) Notice of intent to grant, August 1988, Genetech.

(10) Dr. B. Brody, Animal Patents: the Legal, Economic and Social Issues, symposium presented at Cornell University, 5-6 December 1988.

PATENTING LIFE FORMS: THE LEGAL ENVIRONMENT

Marie-Angèle Hermitte

Original: French

Introduction

The creation of new plant varieties was compensated in a certain number of countries within the framework of UPOV (Union for the Protection of New Varieties of Plants) by the system of Plant Breeders' Rights. This was the case in the 1960s. This temporary monopoly granted to breeders of new plant varieties appeared as an exception to the general and universally recognised legal principle according to which nature was not patentable and life forms were not patentable. The reasons for this exclusion were both philosophical and technical.

When Plant Breeders' Rights were drawn up, the philosophical hurdles were bypassed while efforts were directed to adapting the concept of monopoly over exploitation to the nature of life forms. However, to create life forms you do not start from nothing, but from other life forms. This is why it was decided that there would be free access to protected varieties as initial source of further variation. In other words, to create new varieties it would be possible to use the world's genetic pool without legal obstacles. Plant breeding depended on a vast range of resources including: protected varieties; old varieties of the public sphere; traditional, local cultivars; wild plants that could be collected throughout the world; and plants or varieties found in the big research stations around the world.

From this resulted an established liberty among researchers and breeders to exchange materials on a day to day basis. Public research was a truly public service which put interesting innovations into free circulation, while private firms could work on them afterwards.

On the overall, this equilibrium was satisfactory, despite certain exceptions which appeared as the price of freedom. This balance between public and private research, between accessibility to resources and protection of innovations, is in the process of being brought into question by a hasty legislation calling for the patentability of life forms. On the scientific level, the genetic revolution will surely be interesting if the negative effects are controllable -- which implies taking the time to think. On the legal level, the patentability of life forms, which managed to evolve in the right direction despite earlier positions on the matter, is still far from reflecting any unanimous understanding of biotechnology.

Patents on genes: an incomplete notion of life forms

Plant Breeders' Rights protected varieties that were distinct, homogenous and stable. They therefore applied only to whole, complex life forms that were directly marketable to farmers. Genetic engineering carries forward today a different conception of the living: plants are no longer a combination of genes of which the whole is different from its parts, but are rather seen as a chain of DNA that one can cut into pieces and paste together again as one wishes.

Certainly, everyone admits that that is a reductionist and inexact notion, but the study of interactions, the study of plant physiology, much more difficult than sequencing, is marginalised to the advantage of a linear approach to the genome.

Because sequencing is advancing so much more quickly within the framework of short theses and new successes announced every day, we are witnessing an equally false transfer of the variety to the gene.

First consequence: Research is trying to isolate genetic fragments and functions coded by genes, thus changing the physionomy of investigation. Public research is making it a priority to patent genes, to multiply contracts on applied research, at the very moment when the United States are questioning the limits of the excessive synergy between basic and applied research.

Second consequence: We see a rise of gene merchants, gene salesmen, in the shadow of those who marketed chemical molecules for pharmaceuticals.

We see a rise of gene merchants in the shadow of those who market chemical molecules

Thirdly: By consequence, it must be possible to patent these fragments that are erroneously assimilated to molecules. Those entering the plant market sector —chemical, pharmaceutical and petroleum firms— come equipped with their patent services, their thought habits, and they present Plant Breeders' Rights law as totally inadequate, without understanding how it functions with regard to the protected subject matter.

Fourth consequence: Most seriously, all this is carrying with it a dangerous evolution of the concept of genetic resources. This set of protected, wild and traditional varieties which served plant improvement in the past are now perceived as simple gene reserves to be extracted. What DG-III's Directive —if adopted— would allow would be a transformation of nature into a reserve of genes to be extracted and patented.

Nature, which in the past was free from public or private control, now potentially becomes a reservoir of private property as we can just pull out patentable genes.

On another level we find ourselves now with a resource that is splitting into two different types: on the one hand we have, as before, the wild plant, a complex organism from which we now pull out a gene that will serve to reconstruct other plants. Between the resource and the variety we now have the gene -- intermediary element and unfinished product.

In the earlier enthusiasm of genetic engineering's dawn, isolation of the gene and sequencing of the genome for basic research were regarded as noble objects of creation, the limit of creativity, and it is for this reason that patenting was violently demanded. This phase has already passed. And we are not very far from the day when the choice of the gene promotor will no longer be very creative.

In making genes objects of value we will oblige sovereign States to close their borders to the movement of plants containing these genes

The main obstacles are no longer in the sequencing part of genetic engineering but in the reconstruction of the plant, then of a marketable, profitable variety that can be used by farmers.

The Directive, as well as the practice of industrial property rights institutions, has legally established the vision of the gene as the key element of plant breeding. The consequences that arise from this option:
1. Inequality in the treatment of two professions -- genetic engineering and plant breeding -- will lead to industrial integration;
2. Giving in to the public and private takeover of the planet's genetic resources.

Inequal treatment of two professions

Following the proposed Directive, access to plant varieties —complex organisms— will be free and immediate, not subject to authorisation, which will allow gene holders to have free access to the work of breeders. At the same time, breeders' access to genes will be delayed, subject to both payment and authorisation.

This system lies on the *a priori* holding that the noble invention is the gene. It will logically lead to the takeover of breeders by those who control biotechnologies -- integrated multinational firms who do not impose an agronomic logic defined by the needs of the farmers, but a logic connected to their other activities, which will have particularly negatives impacts in the case of the chemical industry. This tendency is particularly clear in the Commission's Explanatory Memorandum to the Directive: *Science and technology have replaced land and labour.*

This great inconvenience could be moderated if legal thought was allowed to evolve on the question of patenting life forms.

Public and private takeover of genetic resources.

The option in favour of patenting genetic fragments will have consequences that it will be hard to reverse. In making genes, through the intermediary of the patent, objects of value we will oblige sovereign States to close their borders to the movement of plants containing these genes. We will oblige genebanks to regulate and monetarise their exchanges of genetic material. We will also force researchers to stop the flow of genetic material among themselves. I have already witnessed the breaking down of these practices.

This whole movement will grow stronger and harder, putting a full end to the legal freedom of the world's genetic pool.

Conclusion

It is hard to come back to the question of the patentability of genes which, by the way, corresponds more to a type of work than to an invention.

However, this focalisation of interests on genetic fragments and the linear concept of the genome that underlies it, carries with it enormous drawbacks, especially when one considers human beings. Nothing that is done to the plant or

It is not up to DG-III to resolve such a problem, and in fact it is not up to the EEC to do so either

the animal is necessarily far from man. Sequencing of the human genome has already begun and there too, the linear approach to genetics is imposing itself.

When you open the lid on law governing life forms as is being done now, it must be realised that this lid is opening on the whole world of living matter. It is not up to DG-III to resolve such a problem, and in fact it is not up to the EEC, an economic institution, to do so either. We are here at the heart of ethics and of peoples' rights and duties, because there is a continuum from the bacteria to man. The right to speak here belongs to the well-informed representatives of the sovereign people.

SHOULD SEEDS BE PATENTABLE? ELEMENTS OF AN ECONOMIC ANALYSIS

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Original: French

This paper is based on analytical elements developed within the framework of a research programme financed by INRA, CNRS and MRES (France). The findings presented here do not represent final conclusions but a current line of thinking. This text is partly based on an article to be published in the review Economies et Finances Agricoles (review of the CNCA, February 1989). The views expressed here are those of the author.

Introduction

The dematerialisation of the production process constitutes one of the fundamental tendencies of current technological mutations. Take the example of the semiconductor: the cost of the raw materials represents only 5% of the sales price. Globally, in the developed countries, immaterial investment (R&D costs, patents and licenses, training, commercial expenses and software) represent 40% of material investment. The problem of appropriating the economic results of these investments is therefore crucial. Within this context, debates over systems of intellectual property rights are surging up again.

Concerning recent developments in applications of molecular biology, these questions arise in a particular manner as, traditionally, living organisms were not patentable (article 53(b) of the European Patent Convention regarding exclusions from patentability). The legal vacuum within which biotechnologies are being developed will hamper their commercial applications. In this framework, the extension of industrial patents to living beings is often tooted as the best solution. The International Chamber of Commerce (ICC) is particularly representative of this position given that it claims that:
The patent system offers the best perspectives of protecting biotechnological inventions and therefore encouraging research and the acceleration of progress. Through the hundreds of years that the patent system has been with us, no better system, to the knowledge of the ICC, has been constructed and, consequently, we do not believe that there is any need to investigate nor any realistic chance of finding a satisfactory alternative for protecting biotechnological inventions. (In M.A. Hermitte, 1987.)

In fact, the most recent assessment studies carried out show that the so-called absolute superiority of the patent system has more to do with myths and declarations of faith than with objective analysis[1]. We are progressively arriving at a view of the patent as one factor in the competition process. The assessment of patents must therefore be based on a comparison of the dynamic efficiency of alternative systems where interactions between competitive processes, structural transformations and the rhythm and forms of innovation are explicitly taken into account.

The question of patenting living organisms is especially acute in the seed sector. The new techniques coming from biotechnology allow for *deterministic* transformations of plants. For the most part, these techniques meet the criteria of process patenting. Should patents be limited to processes then, or —as is the more general case in law— extend to the products obtained, which in this case are plant varieties? To protect biotechnological inventions is it necessary to patent plant varieties?

To answer this question we will successively analyse three particular points:
1. What are the essential differences between the existing (Plant Breeders' Rights) system (administered by the International Union for the Protection of New Varieties of Plants, UPOV) and the patent system?
2. Attitudes regarding the patenting of plant varieties are controversial. Are patents neutral from the point of view of the evolution of industrial structures?
3. Are patents indispensable (i.e., the only means to create a system that stimulates innovation)? And, finally, given the foreseeable negative effects, are patents desirable?

The absolute superiority of the patent system has more to do with myths and declarations of faith than with objective analysis

PBR vs. patents: the problem posed by the public good characteristic of our genetic heritage.

Regarding the respective impacts of the two systems, it is generally recognised today[2] that they diverge on two particular points:

The first point is the exhaustion of rights in the patent system. In patent law, monopoly rights are terminated once the product in question is brought to market. The enforcement of this rule would undermine any interest in protecting a plant variety by patent. Article 11 of the proposed Council Directive on The Legal Protection of Biotechnological Inventions foresees an adapted interpretation of this principle: *The patent rights would not be exhausted in respect of the use of the crop grown from the patented seeds as a source for the sale of new propagating materials (seeds)*

as this would involve production for the purposes of selling the patented product itself.

The second point is that the principle of successive rights in the patent system is in conflict with the research exemption (article 5.3) of the UPOV Convention. While in the patent system the concept of *dependency* of inventions is used, the UPOV Convention explicitly holds that the breeder's authorisation is not necessary for using the protected variety as the source of variation for developing a new variety nor for marketing that new variety. In this framework, the genetic pool is safeguarded as a purely public good.

Breeders are very attached to this status of genetic resources. They feel that the possibility of building as such on each others' work is to a large extent responsible for genetic progress in agriculture. From this point of view, the Directive opts for a compromise solution. It introduces the concept of dependency licensing, stressing that the *license (...) shall not be available prior to the expiration of three years from the date of the grant of the patent or four years from the date on which the application for a patent was filed, whichever period last expires* (Article 14.2). Such a compulsory license reduces the strength of patents, without, however, modifying the public good status of the gene pool.

Breeders' access to genes will be delayed and subject to both payment and authorisation

We should note that, in reality, patent offices have not waited for legal changes before granting patents that cover plant varieties. The Hibberd case in the U.S.A. (1985) constitutes the first industrial patent protection for a maize variety (tryptophane-rich corn obtained by Molecular Genetics). In June 1988, the European Patent Office (EPO) published its intention to grant a patent to Agrigenetics, acknowledging the firm's claims which cover forage crops transformed through genetic engineering. At the moment, over one hundred patent applications on plants are being examined by the EPO. In the state of current uncertainty as to application conditions and effective scope of these patents, a veritable patent-war, similar to that going on in the field of specialised pharmaceuticals, will quite probably break out.

But given the natural self-replicability of plant varieties, the enforcement of monopoly rights will probably be very difficult here. That is, for example, the opinion of Le Buanec (1987):
From a practical point of view, such an extension (from process to product) would be illusory because we cannot forget that a plant reproduces itself and all you have to do is breed a plant in the secret confines of a laboratory to create a new variety, without it being possible to prove any infringement of a patented process.

In this sense, patents on plant varieties are not only dangerous but they stand a strong chance of being useless.

At stake in the conflict: control over plant genetics by the chemical sector.

To assess the stakes in the conflict, two important observations have to be made. First, the take-over strategy by large chemical firms has partially failed. And secondly, there is indetermination and confrontation between two technical cultures.

The strategy of controlling plant genetics by buying out companies has partially failed.

At the end of the 1970's, plant genetics appeared as one of the strategic poles in the restructuring of the genetic supply industries. This view derived as much from the decline of the agricultural machinery and fertiliser sectors, as from new perspectives for innovation stemming from progress in molecular genetics.

Medium- and long-term perspectives of evolution were therefore quite uncertain. Nevertheless, they did provoke an important wave of buying-out seed firms by the food processing and chemical corporations. Since 1970, over 300 take-overs had been identified in the developed countries.

Despite their numerical importance, the impact of these mergers on the industrial structure and forms of competition have remained limited. The concentration of the market is still weak and capital profits are mediocre.

Indeed, when we look at the largest international seed groups we see that take-over strategies have had a considerable impact. Of the 13 top firms, only four have their main activities in the seed sector *(see Table 1)*. On the other hand, when you examine the entire seed market, you realise that these 13 groups put together only control some 20% of the world market.

Here we find a fundamental difference with the pesticides sector, where the 13 groups account for 70% of total sales. In this sector, the idea of critical size is relevant: with an investment of $75 million to launch a new product, it is estimated that firms whose turnover is under $200 million a year will not be able to remain independent.

In the seed industry, only eight groups attain a turnover that surpasses $200 million. Large size does not seem to confer any absolute advantage -- why? We can consider three factors that explain this:

First, the seed market is highly segmented (doubly divided by species and by geographic zones) to the point that we often find market niches. Given the characteristics of cost functions, a particular market segment can, at the limit, be viable for one firm only. In this case, attacking the established firm can be not only risky, but trying to conquer that niche can be extremely costly.

Second, traditionally, public research is a major source of technology, be it a question of knowledge or improved plant material. Because of the public character of this knowledge, the critical mass of a research group is very low.

TABLE 1 THE PRINCIPAL INTERNATIONAL SEED GROUPS (1982-1987 EVOLUTION, IN MILLIONS OF U.S. DOLLARS)

1982

GROUP	COUNTRY	MAIN ACTIVITY	SEED TURNOVER
[illegible]	USA	Seeds	526
[illegible]	CH	Chemicals	292
[illegible]	USA	Seeds	178.5
[illegible]	S	Food Process.	162.8
[illegible]	F	Seeds	160
[illegible] Shell	GB-NL	Petroleum	150-200
[illegible]	F	Seeds	144
[illegible]	USA	Chemicals	139
[illegible]	CH	Chemicals	119
[illegible]	USA	Food Process.	115
[illegible]	USA	Seeds	100.5
[illegible]	NL	Seeds	100
[illegible]	FRG	Seeds	71

1987

GROUP	COUNTRY	MAIN ACTIVITY	SEED TURNOVER
[illegible]	USA	Seeds	692
[illegible]	CH	Chemicals	382
[illegible]	F	Seeds	234
[illegible]	USA	Food Process.	200-250
[illegible]	USA	Chemicals	217
[illegible]	S	Food Process.	213
[illegible]	CH	Chemicals	213
[illegible]	USA	Seeds	154
[illegible] Shell	GB-NL	Petroleum	150-200
[illegible]	F	Biochemicals	139
[illegible]	FRG	Seeds	127
[illegible]	GB	Chemicals	98
[illegible]	USA	Chemicals	83

Source: *Established by the Author from various sources.*

Thus, as we have seen, protection of innovation has the character of a monopoly which is limited.

Given the current rules governing the game of competition, the establishment of large seed groups is quite expensive. With a fragmented market under slow expansion, internal growth (building up in-house research, etc.) is not very efficient. At the same time, external growth (take-overs) is not enough to bring any decisive advantage to the newcomer firms.

To control plant genetics it is necessary to transform the rules of the game. A strategy of technological rupture, accompanied by a modification of the system of protection of innovation, could allow for this objective to be reached.

Indetermination and confrontation between technical cultures.

Beyond specific research programmes, the global impact of biotechnology on the seed industry or, more generally, on agriculture, is largely undetermined. Everything is happening as if biotechnologies have not yet passed a threshold of reconception which would permit a much clearer view of their development potential (Joly and Zuscovitch, 1988). In this transition phase, technological anticipations depend on technical culture and on established corporate practice.

From this point of view, we can generally distinguish between two types of firms: established firms (specialised plant breeders) and the newcomers (chemical companies and new biotechnology firms).

The plant breeders are fundamentally attached to the concept of plant varieties, as complex polygenic entities. Their know-how derives from a global approach to the plant. For them, biotechnology presents itself as a new set of methodological tools that are to be incorporated in breeding programmes (in vitro tests, somaclonal variation, haplomethods, micro-propagation...). From the start, their attitude toward biotechnology is essentially *defensive*: investment in this field will not be used to disrupt the competitive equilibrium but rather improve their capacities to adapt to such external changes.

It seems that this proposed EEC Directive constitutes a dangerously useless initiative

The chemists generally have a molecular approach to the living world. For them, biotechnologies will represent a mechanism of rupture in the sense that they allow them to move from a macroscopic form of control over plant breeding to a microscopic form of control over genetic engineering. In this framework, they will be able to improve technical interactions between different inputs in order to produce a range of more sophisticated technical solutions. Investment in this field is explicitly directed toward displacing the competitive balance in their favour. These are, therefore, generally *offensive* strategies.

These differences in expectations and the strategic positions adopted are largely determined by the characteristics of the firms in terms of the profession involved and control over research and knowledge.

In the maximalist view, the extension of patents to plant varieties could be interpreted as a modification of the rules of the game in favour of the firms that control genetic engineering. The insertion of a gene would extend monopoly rights to the variety, without the breeder of that variety being able to oppose his own right against the patent. This asymmetry in the handling of two factors of genetic improvement -- plant breeding on the one hand, genetic engineering on the other -- is ambiguous. Despite its efforts in addressing this problem, the EEC Directive does not resolve it.

TABLE 2: DESCRIPTION OF THE PESTICIDES GROUPS (1987, IN MILLIONS OF U.S. DOLLARS)

GROUP	MAIN ACTIVITY	PESTICIDES TURNOVER	R&D BUDGET	SEED RANK	PLANT BIOT. RESRCH	NUMB PAT. APP*
Ciba-Geigy	Pharmaceut.	2037	167	7	***	7
Bayer	Chemicals	1722	140		*	1
ICI	Chemicals	1477	150	12	***	2
Rhone-Poulenc	Chemicals	1464	100		**	1
Monsanto	Chemicals	1178	94		***	8
DuPont	Petroleum	1100	110		***	1
BASF	Chemicals	889	n.d		*	0
Hoechst	Chemicals	833	80		**	4
Dow	Chemicals	820	70		*	0
Shell	Petroleum	754	75	9	**	0
Schering	Pharmaceut.	660	80		*	0
A. Cyanamid	Chemicals	615	86		**	0
Sandoz	Pharmaceut.	550	55		*	1
FMC	Chemic/Arm.	478	67		***	0
Eli Lilly	Pharmaceut.	408	40		**	1

Source: Precepta (Etude Phytosanitaire 1987, Etude Semence 1987).

(*) Patent applications deposited at EPO between 1985 and 1988 in the A01H class (new plants per se); Total applications in this class = 106.

Is is indispensable to patent plant varieties?

The following will present a scenario of evolution based on a hypothesis of technological enhancement strategies. Contrary to what has been observed in the past, it seems that the new biotechnologies do not form a technological paradigm in the usual sense, i.e. *a specific manner of resolving certain types of problems* (Dosi, 1982). The conjunction of three traits determines the generic characteristic of biotechnologies: the great proximity between basic knowledge and applied technology; the multidisciplinary nature of the knowledge involved; and the wide range of potential applications.

We should point out that this phenomenon is not limited to biotechnology but seems to correspond, in the view of many observers, to a new tendency in technological evolution (Gest, 1986; OECD, 1986; Wilinger and Zuscovitch, 1988). In short, we can summarise the main points of this tendency by considering the transition from technological regimes dominated by trends toward standardisation and economies of scale, to regimes where economies of variety allow for the maintenance of a diverse range of products.

If we take this tendency into account, the variety of projects applying biotechnology can no longer be considered a transitory phenomenon of adaptation to an uncertain environment. It could, in fact, point to a permanent characteristic of a technological regime based on the diversity-potential of biotechnology. Indeed, from one basic biotechnique it is possible to develop a multitude of different applications. We could even say that *it is this variability and not any particular application that makes the technology interesting from the start.* In the image of recent developments in computer software industry and in the production of new materials, we can speculate on the emergence of a new technical organisation allowing for the permanent production of a variety of outputs based on standardised inputs (genetic material, chemical molecules, processes).

This hypothesis has very important consequences regarding industrial structures. Contrary to traditional methods of choosing research programmes which lead to the concentration of resources toward one specific application (in order to face rising costs in the passage from research to development), in this case it is essential to maintain a range of technological possibilities and adopt a true strategy of technological enhancement (Gest, 1986). To deal with financial constraints, a company can then look at partnership contracts with other firms who have complementary capacities and specific, necessary techniques. In this hypothesis, the development of partnerships should not be seen as a transitory phase stemming from strong incertitude but rather a permanent characteristic. This leads us to foresee an organisation of industrial networks accompanied by *horizontal* concentration, rather than *vertical* concentration under the control of the chemical sector.

Such a scenario corresponds to a *status quo* from the point of view of protecting innovations. This would appear preferable to other scenarios involving the extension of patents to living matter.

On one hand, the status quo seems satisfactory as regards stimulation to innovate: imitation delays in the seed industry (as in the creation of variety A' drawing from variety A) are from four to five years (distinction and registration delays). It is known that today, a variety hits its peak dissemination within three to four years and has a total market life of some seven to eight years. The combination of these imitation delays and the rapid renewal of varieties leads us to take account of enhancement of technological capacity through a permanent lead in launching new products.

On the other hand, the setting up very strong monopoly positions by granting wide-claim patents could very well block innovation and create situations of preemption. Now, if we are not certain about the advantage of patents as stimulants to innovation, it is certain, on the other hand, that they will bring into question the principle of free access to germplasm and, consequently, the public good status of our genetic heritage.

Conclusion

Many incertitudes persist concerning the evolution of the potential applications of biotechnology and the concrete conditions of enforcing patents on plant varieties.

In the initial analysis, however, it does seem that this proposed EEC Directive constitutes a dangerously useless initiative.

It is dangerous in the sense that it brings into question the public good status of our genetic heritage, thereby disrupting the current fragile equilibrium considered to be particularly efficient. This bringing into question of the public status of germplasm also has important implications in terms of North-South relations as it undermines the sense of the notion of Common Heritage of Mankind attributed by FAO to plant genetic resources.

It is useless in the sense that, taking into account the specificity of living matter, this measure may easily prove to be ineffective. Patents were designed for mechanical inventions. They are totally unadapted to living organisms. In particular, the patent system lies on a compromise between the inventor and society: the inventor is granted a monopoly right in exchange for disclosure of his knowledge. Regarding living organisms, it is hard to imagine how such a compromise could be respected.

It is also useless in the sense that another system designed to stimulate genetic inventions seems viable enough. This one is founded on the maintenance of a permanent lead by an active enhancement of basic technological potential.

NOTES:

(1) For a presentation of the terms of evaluation of the efficiency of the patent system, see Scherer (1980). The work of Levin *et al.* (1984) and Nelson (1986) on the American seed industry show that systems for protecting innovation differ widely according to the sector (trade secrets, apprenticeship, trade blocking) while the patent only acts as one element among others in the competition process. More specifically, a survey carried out among the main pharmaceutical companies shows that the hypothesis according to which Europe's slow performance in the commercial development of biotechnology would be due to inadequacies of the patent system has to be rejected (Angelmar & Liebscher, 1987). Finally, it is worth noting that efforts directed towards an *ex post* analysis of the impact of Plant Breeders' Rights in the United States did not come up with any solid conclusions (Butler & Marion, 1983; Perrin *et al.*, 1983).

(2) See for example Hermitte (1987) and Le Buanec (1987, 1988). Here we will only touch on problems related to the granting of the patent, in particular the rule on sufficiency of description (and thus repeatability) which takes us to the question of deposit of samples and access to them.

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PATENT PROTECTION FOR INVENTIONS FROM AGRICULTURAL BIOTECHNOLOGY

John H. Duesing

Original: English

Introduction

Ciba-Geigy wishes to thank the ICDA, as organisers of the conference, for the invitation to attend and to make this presentation. This is a welcome opportunity to share our views and to mutually educate one another involving our expectations and concerns regarding intellectual property protection for the inventions anticipated from biotechnology.

For this presentation, the organisers have requested that Ciba-Geigy
— describe its general philosophy about patenting agricultural biotechnological inventions, and
— present its position regarding the proposed EC Directive on the legal protection of biotechnological inventions.

The content of this presentation represents the position of the Agricultural Division of Ciba-Geigy and specifically relates to biotechnological inventions involving plants and microbes.

To begin this presentation, I would like to establish a common foundation of definition and information which is necessary to discuss patents for biotechnology products and processes.

What is biotechnology?

First, what is biotechnology? Biotechnology is really a collection of diverse technologies, each developed to better utilise biological systems, that is living systems, for the benefit of mankind. Some of these technologies, such as fermentation and plant breeding, have been part of mankind's culture for thousands of years.

Very recently, genetic engineering has been developed as a new methodology and is being applied and integrated into these existing biotechnologies. The term genetic engineering specifically refers to the process of
— identifying and isolating genetic information from an organism,
— modifying that genetic sequence's informational content or its potential for expression, and
— transferring that modified genetic information into an organism of the same or another species.

This methodology opens up new opportunities for modifying and better utilising our domesticated biological systems.

The objective of applying genetic engineering to plants and plant breeding differs little from the objective of traditional plant breeding. Each method is intended to introduce new genes into the plant which may result in an improved plant variety. The difference lies in the range of genetic diversity available to achieve that improvement. Where traditional breeding has been limited by the barriers of sexual compatibility, genetic engineering makes it possible to create a new insect resistant corn variety using a gene derived from another corn variety or from a wild bean, from a bacterium, and even from another insect.

Therefore, the intent of the traditional breeder and genetic engineer is the same -- to improve the character or quality of a crop plant by the introduction of novel genetic material. The extraordinary value of genetic engineering comes from its ability to bring new, untapped sources of genetic diversity to the effort of plant improvement.

It is Ciba-Geigy's position that legal protection of intellectual property serves the public interest

Subject matter for patent protection

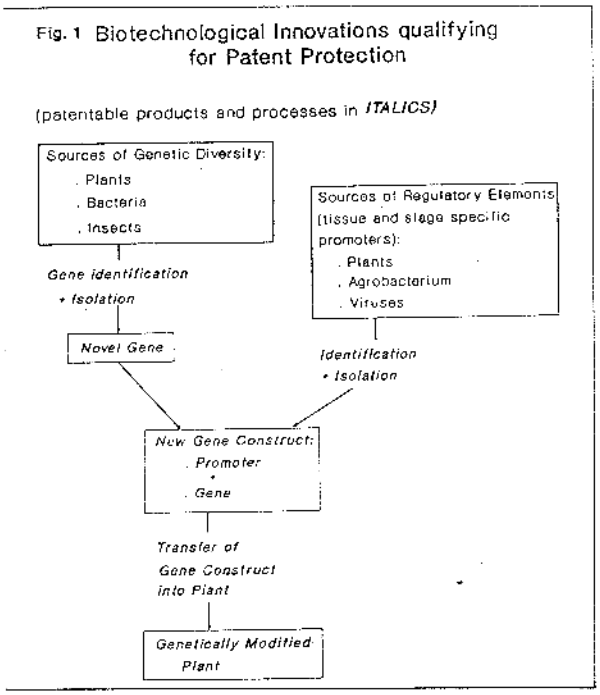
Before presenting Ciba-Geigy's philosophy regarding agricultural biotechnological inventions, it is relevant to review some of the subject matter from plant biotechnology which currently qualifies for patent protection. *Figure 1* illustrates a typical biotechnological effort to genetically modify plants. This effort is actually a complex activity involving many different processes and a variety of genetic materials.

The basic steps include:

— the isolation of specific genetic sequencing coding for proteins and the necessary regulatory information;
— the construction of functional genes with regulated expression and any DNA required for transformation or gene targeting;
— the transformation of the genetic sequence into plant cells; and
— the regeneration of plants expressing the genetic sequence to produce a protein, thereby conferring the desired trait, e.g. pest resistance.

The methods and processes, the genetic materials involved, and the resulting novel plant material from these steps constitute some of the patentable subject matter from agricultural biotechnology.

Fig. 1 Biotechnological Innovations qualifying for Patent Protection



Ciba-Geigy's philosophy on patenting inventions from agricultural biotechnology

It is Ciba-Geigy's position that legal protection of intellectual property serves the public interest by stimulating continuing investment in technological innovation. The protection must apply to all scientific advances, including those from the areas of biology and plant breeding.

Ciba-Geigy is keenly involved in agricultural biotechnology research and firmly believes that the application of genetic engineering and other novel methodologies to the genetic improvement of plants and microbes holds tremendous promise for society. However, this promise will only be realised if the necessary technology can be developed and applied to the fullest with the support of continuing investment. This needed investment will continue as long as adequate intellectual property protection is available for the processes, products and uses coming from that research.

The impact of patents on plant breeding

The availability of patent rights for plant-related inventions has raised questions in three principal areas -- access to biotechnological inventions, access to germplasm, and impact on genetic diversity. I would like to deal with each in detail.

Access to Germplasm. Within the next ten years, seed companies will begin to release genetically-modified plant varieties which will have novel, patented genes for pest resistance or herbicide tolerance. Breeders have asked how the presence of a patented gene will affect their access to the remaining non-patented germplasm in the released variety.

It is Ciba-Geigy's position that the presence of a patented gene in a variety which is not otherwise protected by a patent should not restrict a breeder's access to the rest of the germplasm contained in that variety. This is illustrated in *Figure 2.*

In this example, a variety, which is not itself the subject of a patent right, is commercialised carrying a patented gene. Any breeder is free to use this variety to derive his own new variety and to commercialise his new variety as long as it does not carry the patented gene. Before a breeder can commercialise his new variety carrying the patented gene, he must have the authorisation from the patent holder. This system simply allows a patentee to retain control over any further use of his patented subject matter.

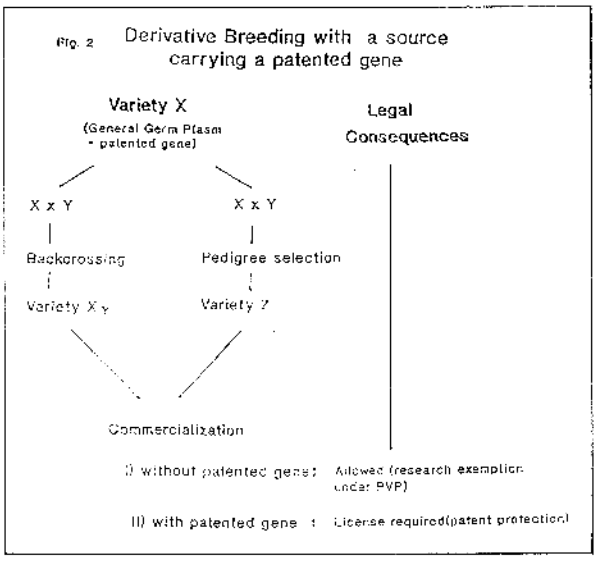
The patenting of novel genes is not intended to restrict the plant breeder's access to the diversity of genetic material

If the breeder is concerned about retaining the patented gene in his final new variety, he can either test during his breeding effort for the presence of the trait (e.g., insect or disease tolerance) conferred by the patented gene or simply start his breeding programme with an earlier commercialised variety which lacks the patented gene.

It should then be clear that the patenting of novel genes is not intended to restrict the plant breeder's access to the diversity of genetic material to which he had access under Plant Breeders' Rights.

Access to Biotechnological Inventions: A related question asked by breeders, especially those with no in-house biotechnology support, involves the general availability of patented genes and processes for their own plant improvement

Fig. 2 Derivative Breeding with a source carrying a patented gene



work. Ciba-Geigy's response to this question is that there are already free-market factors already at work which will ensure wide access to these genetic innovations.

First, there are dozens of companies, large and small, operating agricultural biotechnology research programmes. For strategic reasons or for a lack of capital, a number of these companies are not positioned to participate directly in the seed industry. Moreover, there are many university and public agricultural research facilities which are generating significant basic research results but have no outlet for exploring potential applications for their findings.

Both the private companies and public institutions are looking for partners through whom their results can be commercially exploited. Such arrangements are critical to the private company to harvest a return on its research investment and are especially beneficial to the public institutions to recover some of the public funding which paid for the research and to encourage continued funding of basic research.

Second, it should be emphasised that even those companies, which have substantial in-house programmes of biotechnology research and plant breeding and also have a strong sales network, carry no illusion of being able to cover all crops or all market segments for their target crops. Consequently, these companies will be seeking other sources of income from their technology and will themselves become licensors of gene technology to other seed companies.

Therefore, Ciba-Geigy expects that if a seed company is seriously committed to plant breeding and genetic improvement, there will be sufficient opportunity for it to have access to some of this new genetic diversity.

Genetic Diversity: For the last decade there has been increasing attention to the degree of genetic uniformity within various crop species. Under conditions of crop monoculture across wide areas, this germplasm uniformity can pose a risk to agricultural production. There have been questions about the impact of biotechnology on genetic diversity.

Compulsory licensing will only encourage genetic uniformity

Ciba-Geigy believes that germplasm diversity can best be encouraged and rewarded
— by ensuring patent protection for plants, genes in plants, and novel plant breeding processes, as well as
— by strengthening Plant Breeders' Rights with the introduction of a system of dependent rights, and the application of greater minimum genetic distances for a new variety to qualify for protection.

It is already apparent that within a given project such as insect resistance, there is already intense competition among companies. The importance of this competition is that it results in competing strategies which will, in turn, contribute to the genetic diversity of the solutions. Strong patent protection for novel genes in plants, introduced by traditional breeding or by biotechnology, provides these companies with an incentive to develop their own solution.

Because this strong competition in biotechnology-generated genetic improvement can be expected to prevail, systems for compulsory licensing are not needed to ensure access to these improvements. In fact, compulsory licensing will only encourage genetic uniformity as companies simply make use by derivative breeding of the first or best gene in the market place. The advocates of compulsory licensing might wish to consider the U.S. corn blight of 1969, which resulted from the widespread use of a single, *publicly-available* genetic factor.

Evaluation of the proposed biotechnology patent Directive

Ciba-Geigy wishes to compliment the European Commission on its effort to clarify and unify the scope of patent protection which will be available in the European Community for biotechnological inventions.

Two articles will have a negative impact, practically outweighing the value of the Directive for protecting plant biotechnology

This Directive clearly and directly addresses several issues of concern to Ciba-Geigy. The Directive confirms the following:

1) Patent protection is available for biological substances including those which were previously part of natural materials. When human intervention is responsible for isolating, purifying, and identifying an application for a biological substance, such as a gene, patent protection is available. (Articles 8 & 9)

2) The patent right on genes and processes extends to subsequent generations. As already discussed, any further exploitation of biological subject matter which constitutes or is the result of an invention requires the authorisation of the patent holder. (Articles 12 & 13)

3) Plants and plant material and uses of and processes for the production of plants and plant varieties constitute patentable subject matter. (Articles 2, 3.1 & 4)

Also,

4) The Directive begins to establish appropriate limits on the use of deposits made to support patent applications. Any person requesting and obtaining a deposit may only use it for experimental purposes until a patent is actually granted, and may not use it for commercial purposes if a patent is never granted. (Article 15)

However, there are two articles of the Directive which will have a negative impact, practically outweighing the value of the Directive for protecting plant biotechnology. These two articles are Article 3(2) and Article 14.

Although the Directive has taken an important step by confirming that patent protection will be available for plants and plant materials, the language of Article 3(2) effectively then excludes a vast majority of those plants and plant materials coming from biotechnology.

Article 3(2) will serve to exclude important results from patent protection

Article 3(2) states: *...plants and plant material shall be considered patentable subject matter unless such material is produced by the non-patentable use of a previously known biotechnological process.*

The language of this article could be imposed to exclude from protection beneficial pest-resistant plants created by tissue culture selection or protoplast fusion, if these are considered to be previously known biotechnological processes. Moreover, this article is especially puzzling since in no other technical field are novel products excluded from patent protection simply because a known process was used to create them.

Regarding Article 14, Ciba-Geigy is especially concerned that the effective impact of Article 14 was not entirely foreseen by the Commission when this Article was drafted.

As illustrated in *Figure 3*, the development of a new variety with a patented gene is a lengthy process involving at least 10 years for many crops before the new variety may be ready for commercialisation. Where a novel gene is involved, most companies will apply for patent protection as soon as their research confirms the successful activity of the gene. This is likely to occur during the early research phase. Following the patent filing, a significant period of time is still required for further testing and then for plant breeder's contribution.

Fig. 3 Biotechnological Innovations in the Patent Framework

Activity	No. years	Patenting
1. BIOTECHNOLOGY		
• Transformation etc.	3 - 5	Priority Filing Date
• Greenhouse and small-plot trials	2 - 4	↓
• Regulatory compliance		1 1/2 yrs to publication
		↓
2. PLANT BREEDING		Patent 4-6 yrs after filing
• Development of varieties	[illegible]	
3. AGRONOMY		
• Regional [illegible]	[illegible]	
• [illegible]		
4. MARKETING	11 - 22	[illegible]
• Sale		expires
• Product management		

The plant breeder is responsible for moving the patented gene(s) and trait(s) into locally adapted germplasm and to develop varieties for specific agro-ecological conditions and market needs. The resulting varieties require yield evaluation trials before being submitted for registration. Only when seed of the first variety with the patented novel gene is registered and released on the market is the biotechnology innovator in a position to recover his investment.

Although Article 14 was intended *to recognise the interests of the patentee to enjoy his exclusive rights which provide the incentive for engaging in innovatory activities,* its effects will be exactly the opposite. Eighteen months after a patent application is filed on the novel gene, the patent application is published with the necessary information to recreate the invention. Any company can begin the same process and have the same gene in their own plant varieties ready for commercialisation very soon after, if not at the same time or sooner than, the inventor. The compulsory license at three years from the date for granting the patent, as called for under Article 14(2), effectively eliminates *any opportunity for the patentee to enjoy his exclusive rights.*

Article 14 should be deleted

Ciba-Geigy would hope that if the European Commission is serious about addressing the inventor's right to benefit from an invention in the area of agricultural biotechnology, Article 14 should be deleted. The legislators may also wish to consider measures to restore the patent term where the development and registration time for a new product consumes the major part of the patent term.

If retained, Articles 3(2) and 14 could, instead of actually stimulating biotechnology development in Europe as it was intended, serve to put the European agricultural biotechnology industry at a severe disadvantage in its own territory without compensating opportunities abroad. Furthermore, innovative European agricultural biotechnology firms would no longer be able to offer *and* guarantee an exclusive license for the use of their patented gene in selected crops for Europe. The effective value of establishing exclusive licenses, which would be critical to full exploitation of new genes, would be nullified.

The impact of inadequate protection

A failure to provide adequate protection will have a significant impact on the future development of agricultural biotechnology research and on product commercialisation.

Private Research: Industry would be forced to rely more on trade secret to protect their innovations. Less information would then be publicly available until commercial release of the product. For plants, this could mean 5-7 years of delay before other researchers, private and public, would have access to the results and could build on the success.

Public Research: Much of the agricultural biotechnology research at public institutions depends on support from a partnership of industry, government, and universities. The existence of patent protection makes it possible to establish a proprietary position for the results of this research without unnecessarily delaying the researcher's transmission of his or her results to the research community at large. License and royalty fees paid by industry in the resulting products, support further research at the public institution.

Without proprietary protection, industry could not afford the investment required to take a basic research finding and to transform it into a product to benefit society.

Conclusion

To conclude, I return to the two objectives for this presentation.

First, it is Ciba-Geigy's position that the results from agricultural biotechnology research have the potential to bring significant benefit to society. Those results which meet the criteria for patenting, like genetic materials and plants and plant materials, are entitled to patent protection like the inventions from any other area of technical endeavor. Patent protection will serve to stimulate the development of competing and diverse genetic solutions with access to these diverse solutions ensured by free-market forces at work in the biotechnology and seed industries. The exclusivity provided by patent protection is critical to ensure the full translation of biotechnology research results into improved products for agricultural economies worldwide.

Second, the EC Directive on patenting biotechnological inventions represents a valuable effort to clarify and confirm the extent of patent protection which will be available in the European Community. However, Articles 3(2) and 14 do not support the stated purpose of the Directive. Article 3(2) will serve to exclude certain important results from patent protection. Article 14 will allow foreign competitors to take advantage of compulsory licensing in Europe at the expense of the indigenous plant biotechnology and seed industries. The lack of adequate protection will simply delay the disclosure of important research results and the application of this new technology to agriculture. It is Ciba-Geigy's hope that the Council of Ministers will recognise the deficiencies and negative impact of these two articles and request their deletion from the final text of the Directive.

PLANT PATENTING AS SEEN BY A PLANT BREEDING PROFESSIONAL

Dr. J.G. Boonman

Original: English

Introduction

In no other country do we see so much diversity in activity around seeds but in the Netherlands, one of the world's largest exporters of new plant cultivars. Research, commerce and public debate interact continually in an environment which does not draw sharp dividing lines between private or public, nor between national or international interests.

It was a Wageningen professor who, after a career as a breeder in a farmers' cooperative, initiated legislation to regulate the rights and duties of plant breeders, already before World War II. By that time also, farmers' unions had instituted their bodies to regulate the flow of seed. On a quite different point, many of those now active in the field of seed, (semi-)public or private, have worked for lengthy periods in developing countries, which has helped to promote the national sensitivity to world-wide seed issues. These are only but a few examples of the multiple partnerships on the Dutch-based seed scene. There is no denying the fact that seed has reached great economic heights in the Netherlands and that concern by the public has been equally vocal.

The first month of 1989 has produced some vivid examples of this perpetual interaction:

— A national outcry has erupted against a Wageningen experiment dealing with manipulated mice for which no appropriate license had been sought.

— A conference on the Risk Assessment of genetic engineering drew such a large crowd that the largest hall available in Wageningen was filled to capacity.

— The results of a questionnaire following discussion this winter among 9000 members of the KNBTB, the largest farmers' union in the Netherlands, were published which confirmed the strong reservations farmers have toward patenting life forms.

Similar concerns are expressed in the on-going churches' conciliar process.

— The *Boerderij* farmers' magazine of 27 January published a leading article to state that 5000 plant and animal patent applications are presently being processed in Europe alone.

The proposed EEC Directive

The currently debated EEC Directive on the Legal Protection of Biotechnological Inventions caught most parties, opposing this kind of patenting, off-guard when it was made public. It is still an open question as to how, against the background of known strong opposition against the very idea of patenting life forms from so many interested quarters, a proposal of such far-reaching consequences could ever have come to see the light within the EEC, having originated from one Directorate General. There can be no doubt as to the need within the EEC of harmonising national laws. However, should the interpretation of existing national patent laws and the subsequent initiative of harmonisation go so far as extending to new contents, scope and principles of existing rights?

It is still an open questions as to how a proposal of such far-reaching consequences could ever have come to see the light within the EEC

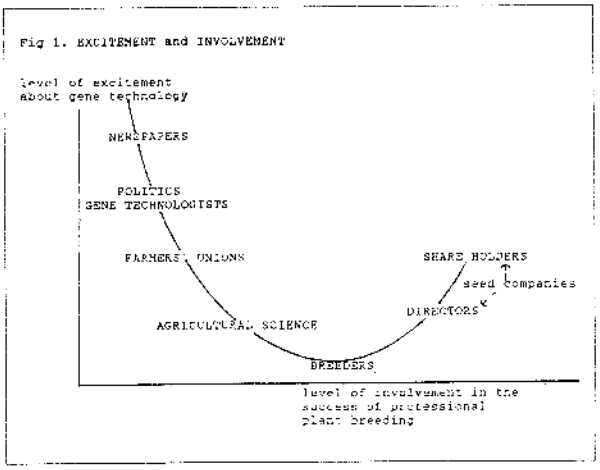
Advances in biotechnology limited

There is a growing awareness that the ticket of biotech has been largely oversold. Many claims of potential did not get further than the form in which they were announced to the press.

The advances in the domain of genetic engineering, popularly called man-made genes, have so far had limited application in plant breeding. Progress may have been somewhat better when it comes to transferring already existing single genes from one plant to another within a few isolated species and has been quite dramatic when we consider technical, diagnostic methods or methods of micropropagation. The latter are, however, essentially biological and not novel. In the current debate we should limit ourselves to man-made genes and gene transfer.

This is perhaps not the forum to debate the advances in the sphere of genetic engineering related to plant breeding as a profession, but discussions would be a lot healthier if the claims made in some circles of biotech are held against the light of actual achievement. We should also take into account the question why certain people say the things they say. In this respect there are clearly two extremes. On the one hand, the newspapers which do not seem to get tired of presenting biotech as a kind of magic. On the other hand, the classical plant breeders, both public and private, who know best the many illusions and pitfalls that characterise working with living organisms, especially plants.

In *Figure 1*, a rudimentary overview has been drawn up of the various parties of people currently taking part in the biotech discussions. It is evident that the level of excitement about the prospects of biotech is strongly dependent on the level of involvement in the success of professional plant breeding. It also goes without saying that those who were not too impressed with the alleged miracles of genetic engineering and even less with the speed with which the claims were to be realised in practical plant breeding do not suffer from sleepless nights about the dangers either.



Whichever course is taken, neither of them is a good financial counsellor. Yet much money and effort has been spent in this field, from unexpected quarters and for quite contrasting reasons. It is tragic to see that much of this is wasted, due to the fact that would-be financiers overlooked the absolute necessity of coupling their resources with those having the know-how of application, agriculture itself, which in turn lacked the finance. Finance, expertise and sense of reality are at present not in the same hands and this will strictly limit the successful application of genetic engineering in plant breeding.

Finance, expertise and sense of reality are not in the same hands

Time is moving fast, in more than one sense. It is no less than 15 years since genetic engineering made itself widely heard. This length of period happens to be the timespan at the end of which the classical breeder usually decides whether or not to continue on the course he has set upon.

On balance, there is still no cultivar in the hands of farmers with man-made or transferred genes. The deadline date keeps being pushed forward to within the next two or three years. Many gene-tech companies, however, have come and gone.

Plant breeding as a profession

Hugh Doggett, one-time sorghum breeder in East Africa, spoke of a profession of ennoblement. The plant breeder channels the flow of evolution, as tenant of the heritage of previous generations.

Most of Europe's traditional plant breeding companies have their roots in seed growing activities, and were almost equally divided between cooperative and private organisations, the latter mostly family enterprises by origin. However, breeding and seed trading became more strongly united and received a considerable boost following the adoption of the 1961 UPOV Convention, regulating Plant Breeders' Rights (PBR).

Some companies like Zelder were specifically founded after World War II for the breeding of better cultivars for the members of the cooperatives involved. In some countries, e.g. the U.K., breeding was largely in government hands until quite recently and this is still the predominant situation in developing countries, with an important role being played by the international institutes such as CIMMYT and IRRI. In the last two decades, many family seed enterprises, especially in horticulture, have been acquired by transnational, mostly petrochemical, companies. Finally, there are very few examples of new breeding companies being founded other than through expansion or acquisition.

The disappearance of small breeding companies should be regarded as a great loss to plant breeding

There is no easy answer to the question of what, from the public point of view, should be the ideal umbrella of plant breeding. The question may, after all, be totally irrelevant. Clearly, there are justifications for each and every situation. However, it seems clear that if governments should feel the urge to initiate what is new or to control what is already out there, they should be equally prepared to step back and make room for private initiatives. Government monopolies are no better than any other.

Preservation and open exchange of genetic resources

None of the above alternative forms of organisation provides a free ticket to the conservation, let alone exchange, of genetic resources. There are, in today's world, notorious examples of bureaucratic, impenetrable genetic fortresses which the public would suspect least and last. Again, there are no easy answers to the problem of genetic erosion. Conversely, equally unexpected to many may be the experience of countries -- which have adopted Plant Breeders' Rights and which have therefore subscribed to an internationally well-established regulatory scheme of seed flow -- that they have access more readily to the breeding achieve-

ments of partner countries. Consequently, in the light of the threat posed by plant patents, it is of vital importance that such schemes be promoted rather than held suspect.

Breeding for resistance

Every plant breeder undertakes the development of resistance against pests and diseases as a priority in his programme whether there are acceptable biocides or not. Susceptible cultivars have little chance of entering commerce, even if they have passed the regulatory testing. Contrary to widespread belief, however, there is little benefit to be gained from the direct use of alien genes in plant breeding. Alien is here meant to denote genes that are distant both geographically and historically. This is, in quite a different context, a lesson gene technologists are just beginning to learn the hard way. Breeding for characteristics such as adaptation and yield involve countless numbers of genes, which are, by definition, hard to manipulate.

Just as it is a fallacy to assume that modern uniform plant cultivars are *per se* less resistant to disease, it had equally been shown that modern cultivars may well be the best choice under intensive and extensive growing conditions alike. Proof of this phenomenon can be found in temperate and tropical environments, where farmers are free to choose. Biological farmers in the Netherlands chooses, perhaps unknowingly, the same wheat variety as intensive farmers do. In Kenya, tremendous strides in feeding the nation have been the result of widespread adoption of hybrid maize by peasant farmers.

Who will have the guts to declare a gene novel and non-obvious?

It should not be forgotten that breeding is essentially a step-by-step approach, without shortcuts. The process starts as it always did with the local landraces which are gradually enriched and matched with alien genes. Every new cultivar may contain the key of success of those to come. Let it not be forgotten that many valuable resistance genes of old varieties have been retained in today's cultivars through this very process of step-by-step improvement. This is why the classical plant breeders regard the interest of free availability -- of cultivars for the development of new cultivars -- as paramount.

Small breeding companies

The availability and diversity of genetic material are probably best preserved if breeding activities continue to be spread over as many independent public and private bodies as is economically possible. It is an established fact that right up to this date, the most popular new cultivars of the important (food) crops continue to originate to a large extent from traditionally well established, relatively unscathed breeding companies. Many of these are still quite small and, on an industrial scale, indeed very small. This holds true definitely in Europe for cereals, potatoes, pulses and grasses. Conversely, many of the petrochemical companies which have entered the seed business through acquisition of existing firms have seen their share of the seed market diminish.

The results of a questionnaire confirmed the strong reservations farmers have toward patenting life forms

Plant patents: What is the buzz?

From the above, it could be argued that the advocates of legal protection of biotechnological inventions have little ground upon which to base their claims of any reward for outstanding achievement in the field of plant breeding. In fact, the disappearance of small, yet successful, breeding companies into transnational petrochemical companies should be regarded as a great loss to plant breeding as a profession, since resources and emphasis will probably be diverted away from plant breeding into genetic engineering. With this in mind, the question should be asked whether it is not somewhat premature for the EEC to formulate a proposal which, if implemented, may serve imagination more than anything else and which will certainly destroy much of what has been achieved thus far in plant breeding and particularly in regulating a system of exchange of genetic material to further the aims of breeding.

Of course, there are those who outright reject the patenting of any life forms as utterly repugnant and morally degenerate. However strong many of us may sympathise with this in principle, it may not be a helpful argument to face opponents with. Is it necessary to go quite this far?

What is so different in 1989 A.D. from the 1960s or 1970s when detailed studies and discussions led to the virtually unanimous decision to exclude plants (and animals) from patent law? Is it because so many have now invested so heavily in this field?

Technical objections to plant patents

The plant breeding profession has monitored for years the developments in genetic engineering and has made great strides in formulating an adequate reply as regards the legal protection of biotechnological inventions. The discussions among plant breeders have taken place at the EEC level (COMASSO) and at the international level (ASSINSEL). Complicating the issue were matters such as: patent rights already existing for micro-organisms; the fact that some breeding companies now form part of petrochemical, transnational companies; as well as the difficulty that national laws differ substantially from one another.

Outsiders might have assumed that plant breeders would opt for patent rights, simply because patent rights would afford a stronger protection than the prevailing system of Plant Breeders' Rights. However, this assumption is beside the truth. Patents are seen as detrimental since they would restrict the (commercial) use of such protected cultivars for agriculture and, most importantly, for the development (e.g., through crossing) of new cultivars, a right which is now free under the UPOV Convention (Plant Breeders' Rights). Under PBR, anyone is free to cross his cultivar with any other and commercialise it. This is of paramount importance for the progress of plant breeding.

It will not be necessary here to repeat the main features of a product or process invention to be patentable under existing patent laws: novelty; non-obviousness; description or deposit; reproducibility; exhaustive rights. A few remarks and questions may suffice.

Product: Only the manipulated gene and not the organism into which it is transferred? What if the gene is there but does not work?

Process: With the exclusion of essentially biological processes (self-replication) as most patent laws have it at present? With the exclusion of the immediate product of the process, be it micro-organism or plant cell, plant tissue, the plant itself or variety, let alone the final consumers' product? In plant breeding processes, it is a well known fact that different products arise even if the processes and basic material are of the same description, simply because of natural shifts and mutations. Such process are, therefore, not reproducible.

Novelty and non-obviousness: Who will have the guts to declare a gene novel and non-obvious? Would anyone know enough of genetics and nature to claim such arrogance? There is little likelihood of any new functioning gene being invented as novel.

5000 plant and animal patent applications are presently being processed in Europe alone

The EEC Directive on the Legal Protection of Biotechnological Inventions has added fuel to the already existing confusion of definitions by introducing terms such as *classifications other than varieties, mixtures as subject matter of inventions, experimental use, uses of (...) varieties or processes for the production thereof.*

It seems an almost impossible task to reach a consensus on definitions there where the interests clash. That was exactly the reason why plants and animals have thus far been excluded from patent laws.

It is quite well possible that agreement will be reached on minor definitions, which will then clash with the major ones. For instance, ASSINSEL and COMASSO will not at all cost oppose the idea of patenting genetic components (genes) or manipulative methodologies, nor against a proper remuneration of the patent holder, provided that such protection is not extended to the relevant host entity (cultivar), and provided that the genetic components, if patented, are unrestrictedly accessible and/or usable for developing new cultivars.

It would be unreasonable to expect a breeder to sit back and watch his cultivar travel freely (under PBR) to potential patent claimants who after adding a gene may bar him (under patent law) from exploiting his proper rights.

This proposal will certainly destroy much of what has been achieved thus far in plant breeding

The debate goes on and the statement is often made that a solution should be sought in removing some of the restrictions which are inherent to the PBR system by adapting the UPOV Convention, e.g. by introducing the element of dependency and cross licensing and by ensuring that all forms of propagating material derived from a cultivar and identical to it should be protectable through the title of protection applicable to that cultivar.

Conclusion

The EEC initiative on the Legal Protection of Biotechnological Inventions is a highly controversial one because of a lack of clear definitions. In its ultimate consequences, the proposal opens the door to the patenting of cultivars themselves, thereby excluding the open exchange which now prevails among plant breeders. For the plant breeding profession, this is unacceptable.

FROM CABBAGES TO KINGS: INTELLECTUAL PROPERTY VS. INTELLECTUAL INTEGRITY

Pat Mooney

Original: English

Introduction

The current EEC proposal for the patenting of life forms is rather like the much discussed release of a genetically-altered organism into the environment. Before permitting its release, EEC Commissioners would be well advised to, first, determine what is out there in the ground already and, second, have some data on the likely impact of their release on the wider environment even beyond Europe. I will argue that what is on the ground now in the form of other monopolies over life show that another EEC release would adversely affect the R&D environment in Europe. Further, the impact of the release on the environment beyond Europe -- particularly in the Third World -- could result in a build-up of resistances that could permanently damage innovation in the Community.

Biotechnology is not just genetic manipulation. It is tissue culture, cell culture and everything else. And I think that it is quite legitimate for society to pursue biotechnology in its widest context on behalf of its own interests in a broad and public discussion.

The approach to the question of who should do the work is that society should first of all say to itself: what are our problems? Some of those problems need scientific help, they need, probably, biotechnology to assist them. Once we decide what the problems are and what technologies we have available to us, we can then say here we need these new technologies and there the old ones worked very well and are safer. Once we decide that, then society should say: to what degree should the public sector take this initiative and to what degree do we need the private sector? I am sure that we will come in many cases to say that the private sector has a role to play on all of this. We need to also harnass that engine.

And then we can ask ourselves: what kind of incentives do we need to give the private sector in order for them to do this? Incentives can mean many things including subsidies. And in the range of those subsidies it is legitimate for society to say: we can choose tax incentives, breaks of different kinds, holidays from taxes, free facilities, science parks, support for higher education, management training programmes, employment programmes, export supports for the technology. Many possibilities are there -- including the subsidy known as intellectual property.

Within the area of intellectual property, though, if we get to that declension in the discussion, society should say: do we want to give innovators *exclusive* monopoly protection or simply give them an inventor's certificate, for example, or some non-exclusive protection for their intellectual property?

I have always found it amazing to me that industry not only says that they want to reap a return on their investment but they also want to have exclusive control over it, rather than simply obtaining the royalties. I think that they have to explain why it is that they do not just want royalties but they want to monopolise their intellectual property at the same time. If industry can then justify to society why it is that we should do all those things for them and we think it is worthwhile as a society, then let us do it. What is now happening with the discussion on the EEC Directive is that all of those logical steps are being ignored. The EEC is simply saying: let us give industry exclusive monopoly control over life. And that is stupid.

Society's struggle with patenting

Looking at the history of the discussions on patents, especially in the area of the industrial patent system, back in the 1850s through the 1870s, there was a very intense debate within society as to the value of industrial patents and the threat of industrial patents for the safety of research and innovation in Europe. I have read the debates that took place: Bismark, for example, attacked the industrial patent system as being negative to innovation; the British House of Lords attacked the patent system for the same reason; the Swiss Parliament described the patent systems as being a pernicious system working against the interests of research.

There was a long, intense debate over this and when the patent system was finally formalised in the Paris Convention, it was done with all kinds of warnings and concerns about its limitations, and expressions about the need for compulsory licensing, etc. At that time it was clearly understood, in an environment of strong religious views prevailing in Europe, that the patent system was to be confined to the industrial sector.

Industry not only says that they want a return on their investment but they also want to have exclusive control over it

Then we find, some years later on, that those producing ornamentals and fruits began to argue that they should be allowed to have their equivalent of a patent system. And again it was understood clearly that we would never think of patenting food crops. That was the limit of acceptable ethics: fruits and flowers, maybe, but not beyond that.

By the 1960s, the ethical concern that we should not go beyond fruits and flowers had changed to the possibility that we should be able to patent food crops. And we were told again during the debates in the 1960s and the 1970s that we would not go further, that it was nonsense to talk about the patenting of animals or pets. This was beyond social acceptability.

Now we are at that stage where one more declension has been made and the EEC Commission is prepared to accept the concept of patenting higher life forms. Today again, we are being told that we will not go beyond this, that we would never consider the patenting of, for example, a human being.

In the discussions in the first panel this morning, the ethical debate over history was ignored and what we were being told was that the ethics had remained throughout. It was presented as only a technical question as to whether or not we can practically, mechanistically recognise, identify and employ patent rules related to life forms. The ethics have not been involved at all.

Except for one thing. We heard in the first panel that now, for the first time, ethics are involved. The European Commission will not allow the patenting of human beings because of ethics. We are asked to believe once more that we will not go beyond this stage, that this is as far as we will go. I think society was told that several times in the past, in the 1930s and in the 1970s, and we are being asked believe it one more time. I do not think we should.

The scale bias

I think it is important to look at where we are going with agriculture, and what sort of strategies and roles the patent system plays as we look at future developments in agriculture. There are a couple of very important points to stress about patents that have not been stressed here.

One of them is that the patent system is scale-biased toward large enterprises over small enterprises. The reason for that is, in part, the number of lawyers they can get involved in the exotic area of litigation. When a big company comes up beside a small company and says, *That cow (or that plant) looks a lot like mine. Do you want to fight about it?* The big guys have a lot more lawyers than the small guys, and even if the small enterprises might someday win, they will be dead by then, they will have gone out of business. There is a scale bias in here that has to be recognised.

Patents, in fact, reduce innovation

Secondly, we have to recognise that another part of that scale bias is the ability for large enterprises to use the exclusive monopoly to exclude small companies. If you are a multinational enterprise with products in numbers of areas, in pharmaceuticals, in specialty chemicals, in textiles, in plants and animals, etc., and you a have a number of licenses or patents available that you are working with, who do you exchange those licenses with? With a single-product small enterprise that can only trade with you one license for one license? Or do you work with another multinational company, also with a wide range of products and geographical emphases, and exchange your licenses with them?

It makes more sense to swap, perhaps, your chemical patent license with another company against their animal patent license. Who cares? The point is the range of negotiations between the large enterprises far exceeds the capacity of the small enterprises to match. And therefore the patent system works in favour of cross-licensing among the multinationals, keeping out the small and creative innovaters.

When Hoffmann-LaRoche got its patent on Valium, it went to sleep for seventeen years

The result of all this is the kind of thing that the *Wall Street Journal* described a few years ago for Hoffmann-LaRoche, the drug company. They pointed out, and this is their terminology, that when Hoffmann-LaRoche got its patent on Valium, it went to sleep for seventeen years. Essentially, they overdosed on their own product. There was no requirement to be innovative. They had their patent protection and they could rest upon their laurels. In the end, the only inventive activity around patents lies in trying to extend the years of patent protection and inventing around someone else's patent. Society suffers and has to pay the bill.

I think it was Voltaire who described hanging as wonderful because it could really concentrate the mind. Patents are the same way. They concentrate the mind upon those things that can be easily patented and defended in the law court. I do not think that is the way society innovates. Patents, in fact, reduce innovation.

Intellectual integrity of the Third World

The intense discussion over the patenting of life forms in Europe has found an echo and an analysis in the Third World. Within the past month, two important conferences in Africa -- one for SADCC in Harare and the other for scientific institutes in Nairobi -- have both targeted the life patenting trend and proposed strategic responses with serious consequences for European innnovation. The question of life patenting is also expected to take centre stage at an FAO conference in Rome in the spring and at a UN Environment conference in Nairobi in May.

Central to Third World concern is that European and American patent proposals ignore the fact that the raw material -- as well as much of the intellectual work -- of biological products and processes originate in Africa, Asia and Latin America. Genetic materials are the irreplaceable ingredients in genetic engineering and, as Third World countries are well aware, the overwhelming majority of genetic material is found in developing countries.

Although biotech companies have tended to argue that material from the Third World is stone-age germplasm without value, both scientists and ethno-botanists have come to recognise that cultivated and medicinal plants, as well as other plants adapted for specialty purposes, are the product of genuine human genius. This is not merely traditional wisdom but actually represents work in progress as Third World farmers, gardeners and herbalists continue to innovate today.

Indeed, the argument that intellectual property is only recognisable when performed in laboratories with white lab coasts is fundamentally a racist view of scientific development, made even more absurd by the famous Chakabarty decision which allowed Northern scientists to obtain intellectual property rights over any natural material isolated by a researcher. Farmers, gardeners and herbalists use this much inventive genius and more as they continually modify and develop new plant, animal and microbial products and processes.

At a conference sponsored in part by the African Association for Science just ended in Kenya, it was unanimously agreed that the informal intellectual integrity of Third World innovators must be protected by their governments and that this viewpoint should be taken both to WIPO and to UPOV.

The EEC is simply saying: let us give industry exclusive monopoly control over life -- and that is stupid

Europe should understand that the South has a credible case and that Third World countries are pursuing this course as a defensive initiative against the threat of laws in the North that will allow genetic raw materials anywhere in the world to become the property of private interests. The African meeting also proposed that access to genetic materials be restricted on the basis of exploration and export licenses and upon contractual arrangements covering the exchange of scientific information and a percentage distribution of wealth created through the genetic material.

I think that all this is going to make something of a mess of the so-called intellectual property system. And the blame, of course, will be put on the Third World. But the blame, I think, belongs with the EEC Directive.

Monopolies on food

Where are we going with all this in terms of the food system? I would guess, because of the monopolistic aspects of the patent system and the way I have described the ability of the multinational companies to employ it more effectively than small companies, that in the near future, the food system will be controlled by a few food processors. We will have perhaps half a dozen to a dozen here in Europe, another half a dozen in North America, a few in Japan and some elsewhere. Those enterprises will control the food system as processing companies. In fact, I think at the end of the day Ciba-Geigy, for example, will be bought by Nestlé and Sandoz will be bought by Unilever because the agricultural input companies really do not have the same capacity to profit from biotechnology as the food processors do. The latter can make money at all steps of the system.

What we will see then is farmers being offered not seed anymore, but encapsulated embryos. This is already possible. Crop plant embryos will be encapsulated in a gel with the herbicides, fungicides, insecticides, plant growth regulators and so on, thought by the company to be required by the farmer. The farmer will simply be in a position of renting germplasm from the food processing companies.

This is a pretty dangerous system. We have heard two references so far today about the work being done on insect resistance, both times being described to us as means by which we would reduce the amount of crop chemicals required in agriculture. In fact, about half of all of the work being done by all of the companies related to biotechnology in agriculture is to develop herbicide-tolerant plant varieties, thus increasing the possibility of using more crop chemicals, not reducing it. And even much of the work related to insect resistance using *Bacillus thuringiensis* is work which could very easily see a rapid increase in the resistance capacities of the insects and in a greater requirement for chemicals. Most of the so-called benign work on natural forms of pest control are not to replace crop chemicals but are, in fact, to be added to existing uses of pesticides, not to replace them at all. So the strategy will be one of a greater use of chemicals.

I worry about all this in the context of patenting. It is going to facilitate even further this type of monopoly control and, again, mean far fewer choices for us in the food system than we have ever had before.

Conclusion

All of these elements have to be looked at when we look at the direction in which we should be going with adapting patent law. Most of all we should not forget the history of the patent discussion. I think it was Milan Kundera, the Czech poet, who said that the struggle of people over tyranny is the struggle of remembering over forgetting.

At every point in history where we tried to accomodate the patent system, we have lost out

In the last century we have had a long struggle with the patent system. At every point in history where we tried to accomodate it saying, *okay, go ahead if it only goes this far,* we have lost out. I think the greatest loss was over Plant Breeders' Rights where, again, it was stressed that this was only for plants, and we would go no further. In fact that was the starting point that has allowed industry and the EEC Commission to say to us now: *You have already accepted the patenting of life there, why not on life when it comes to animals?* And then why not ourselves? We cannot afford to be naive about this, there is far too much at risk.

INDUSTRIAL PATENTS, PLANT BREEDING AND GENETIC RESOURCES: A PLANT BREEDER'S VIEW

Dr. J.J. Hardon

Original: English

Introduction

It is with reluctance and almost a sense of irritation that I participate in this debate on legal issues around genes.

Genes are the primary resource of plant breeding and one could say that free availability of those genes for the purpose of crop improvement is something like a constitutional right. A right going back 12,000 years to the dawn of agriculture and the domestication of all those crops we grow or have grown. These crops are the result of the efforts of countless generations of farmers, selecting, exchanging materials and introducing and adapting them to new environments.

Domestication as an evolutionary process transformed wild species to forms that differed more and more from their progenitors: non-shattering of seeds, larger inflorescence, larger seeds, more uniform ripening, increased percent seed set and so on. Modern technology has increased the efficiency of using such diversity. First through plant breeding, based on our understanding of genetics, followed in the past decade by understanding and starting to be able to manipulate the hereditary characters at the molecular level. This provides us with ever more powerful tools to manipulate and adapt living organisms to what we want them to do.

As plant breeders, we are of course tremendously excited about the new possibilities which modern biotechnology offers us. New characters will be added across species barriers, new forms of disease and pest control will become available, more rapid ways of propagating our breeding materials and so on.

If society wants the private sector to play a role in such research, then obviously there must be some form of reward for achievements to provide the necessary incentives. The Draft Council Directive on the Legal Protection of Biotechnological Inventions was drawn up for this purpose. It reached the agricultural research community in an almost final form. I am not aware of extensive prior consultation with colleagues in plant breeding or those responsible for collection and conservation of genetic resource. Hence we see a rather one-sided set of proposals stemming from an industrial research philosophy aimed at competition, control and exploitation for corporate profits, as opposed to the more moderate philosophy of agriculture in which the position of farmers, consumer interests and society as a whole weigh heavily.

I will not go into legalistic interpretations of the present Directive. That seems hardly necessary since almost anything touched on by some kind of biotechnology is considered patentable, including genes and biological processes in plants and animals. Just some general observation on the latter.

Surely the identification of a specific gene or biological process is a discovery and not an invention

I have always understood that for something to be eligible to patent protection, two basic criteria have to be satisfied: it has to be non-obvious and it has to be an invention and not a discovery. Both criteria would seem to rule out genes and essentially biological processes. A finite set of enzyme systems regulated by similar genes across genera, families and taxa determine processes in plants. That some of them appear non-obvious at present mainly reflects our lack of knowledge rather than that such systems in themselves are non-obvious.

Secondly, surely the identification of a specific gene or biological process is a discovery and not an invention. Furthermore, in industrial patents, basic raw materials are left out and only specific applications are protected. Genes, even if modified as a consequence of some biotechnological method should still be seen as basic raw material. One wonders why these important criteria are interpreted in such a relaxed manner in the Directive and who is meant to profit.

Ignoring above criteria, the actual Directive itself strikes me as totally inconsistent in the context of industrial patent legislation. In its present form, it will undoubtedly stimulate private investment in biotechnological research and rapid development of market-oriented applications. It will strengthen the role of private industry in plant breeding even if biased to the larger companies. These may be positive effects with some qualifications.

The questions I have are concerned with wider aspects of agriculture and more particularly with the effect it will have on food production, plant breeding and the availability and use of plant genetic resources. I will merely raise those questions and attempt to put them into a proper perspective. I hope it will help the responsible authorities and politicians to prepare a legislation that does what laws are supposed to do: to provide rules that benefit society as a whole, and not just a segment of the industrial society.

Stewardship or ownership?

As crops evolved and improved, they spread over climatic boundaries, crossed geographical barriers, mountain ranges and oceans. Countless generations of farmers applied their skills and left us numerous landraces. These are a truly common resource available to and shared by all.

By the twentieth century, science, technology and industry began to work together in support of agriculture. Plant breeding became more complicated and costly, and a private seed industry started to demand legal protection of new plant varieties in order to attract the necessary investment. Several international meetings were held between 1957 and 1961 resulting in the Convention of the International Union for the Protection of New Varieties of Plants (the UPOV Conventions, Paris, 2 December 1961), signed by Belgium, France, Italy, the Netherlands, and the Federal Republic of Germany, under the aegis of the World Intellectual Property Organisation (WIPO), a specialised agency of the United Nations dealing with patents. In 1978, membership of UPOV was extended to non-European countries and in 1989 there are 17 member countries including most West European countries, the U.S.A., New Zealand, South Africa, Japan and Israel. These countries represent over 70% of seed sales in countries with a market economy.

What is, however, of direct relevance to our discussion here is the extent of the protection given by Plant Breeders' Rights deviating from common industrial patents and the reasoning behind it. Central to this debate was the generally accepted notion that there was reason to reward a breeder of a new and useful variety for his work, but that society should benefit in a more general sense as much as possible from such breeding activities.

Exclusive ownership would not be in the general interest

Throughout these discussions, the special nature of plant varieties in food production was stressed. There was general consensus that too restrictive and exclusive ownership would not be in the general interest. Furthermore, it was argued that plant breeding makes use of commonly available genetic variation. Hence it is quite likely that different programmes may yield identical results. For this reason alone, in plant breeding, an exclusive right was not considered appropriate.

Plant Breeders' Rights provide legal ownership of a new variety for the purpose of multiplication and sale of seeds, but in the case of a general interest, a license arrangement may be enforced for a reasonable fee. It does not prohibit farmers from using part of their own crop for next year's sowing. Finally, a legally protected variety may be used for the purpose of further breeding without the consent of the owner of that right. These articles illustrate the careful consideration given to provide plant breeders with a reasonable reward for their contribution, but at the same time this should not hinder or restrict the use of such results for the common good.

It perhaps reflects the attitude of an industry at that time still closely linked to the agricultural community and their sense of values. Plant Breeders' Rights has not failed in its objectives. Plant breeders seem in general satisfied with the UPOV Convention although there is a demand to repair some holes in the system. Countries that adopted such legislation generally saw an expansion of investment in private plant breeding.

Public versus private plant breeding

ICDA in the early 1980s, as part of its Seeds Campaign, criticised Plant Breeders' Rights as a mechanism through which the industrial North could gain control over seed production in the South. However, it should be realised that PBR, even if harmonised through the UPOV Convention, remains a national law not extending protection beyond national boundaries. The real question is whether, and if so, what role private industry should play in plant breeding and seed production.

This is a very relevant question for many developing countries. Unlike in the industrial North, plant breeding in most developing countries is done by government institutions and internationally by crop research institutes supported by the Consultative Group on International Agricultural Research (CGIAR) -- a group of donor countries and foundations led by the co-sponsors FAO, UNDP and the World Bank. It has resulted in a large, successful publicly financed and truly international activity in plant breeding.

The question may be asked whether we deal here with a consequence of under-development or whether the combination of a public-financed international network of International Agricultural Research Centres (IARCs) in cooperation with National Agricultural Research institutes (NARs) provides a viable alternative to, or at least complements, private industry plant breeding. There can be little argument that most IARCs, in cooperation with NARs, are as effective in making available new, higher yielding varieties of crops.

The combination of genetic resources conservation with plant breeding, and the free availability of both private and advanced breeding materials tested in extensive international breeding programmes, is a considerable advantage of smaller competing private industry programmes, working often with more restricted genetic variation.

Finally, setting research objectives can be based on national priorities of development. Private industry would naturally direct its programmes primarily at the more resource-rich farmers and regions, leaving poorer farming communities, specifically in the less favourable environments, further behind. A possible advantage of private industry could probably be in seed production and distribution. Relevant to the present discussion is the necessary conclusion that equity in development seems to suggest the need for public financed plant breeding research in the Third World for some time to come. Free availability of breeding lines and other research results reduces the need for legal protection. However, if private industry is to play a role, in-

centives by some form of property right should probably be provided.

I dwelled on this to illustrate the important role public institutions can play in agriculture. Let us not forget that most of the breakthroughs in modern biotechnology have come from universities and other public institutions. So far, private industry largely depended on entrepreneurial scientists taking their expertise and even sometimes their results from such public institutions.

This is not meant as a criticism of the role private industry plays or can play in agriculture. Without their contributions we would not be able to feed the world today. However, their contribution should be seen in a proper perspective.

Biotechnology

The stage is now set for discussing the possible impact the proposed EC Council Directive on the Legal Protection of Biotechnological Inventions, if adopted in this form, may have on plant breeding and genetic resources.

The proposal is clear. It has strong support from major groups of agricultural industries, which have been dominating the seed market in the industrial market-economy countries since the 1970s and have invested heavily in biotechnology. The objective is to strengthen the protected ownership of methods, products and processes resulting from biotechnological research along the lines of industrial patent laws. This is not surprising. It illustrates that plant breeding and biotechnology have moved out of the control of the agricultural community into the international industrial complex.

We are in the fortunate position that inferences may be drawn from how this industrial complex coped with its role in the development, production and application of chemical pesticides. Ample examples are also available how it interpreted its responsibilities in the marketing of pharmaceuticals, notably in countries that lacked adequate governmental control mechanisms. The research scientists of these companies must have been aware of the dangers some of these substances presented to man and the environment if applied in excess. Being ordinary and responsible citizens, they probably pointed this out but, obviously, decisions were often taken by others responsible for marketing.

Free availability of breeding lines and other research results reduces the need for legal protection

This should not be seen as a fraudulent attitude of industry, but mainly as an indication that the primary objective of private industry is and must be corporate profits within the law. It took universities and public institutions, including the FAO, to develop ways of integrated pest control and moderate reliance on chemical means of control. It took the World Health Organisation (WHO) and non-governmental organisations (NGOs) to try and curb the unbridled marketing of pharmaceuticals beyond the needs and financial capabilities of the poor. In short, what is needed are reasonable checks and balances. In plant breeding, Plant Breeders' Rights legislation provides such checks and balances and avoids monopoly situations. It is hard to see such checks and balances in the present draft Directive of the EEC where it affects plant breeding and, thus, food production worldwide.

Patenting genes completely undermines the basic principle of free exchange of genetic resources

I already indicated what possible benefits might stem from industrial patent protection in biotechnology. Let us now look at some implications that might slow down or bias developments in crop improvement if the Directive were to be applied in its present form. My comments are meant to be indicative rather than provide an exhaustive analysis. That still needs to be done, in fact should have been done by those who drafted the Directive.

Plant breeding institutions and genebanks worldwide are involved in collection and evaluation of genetic resources in a constant search for new characters and genes important to crop improvement. Results are freely published. There is wide consensus among plant breeders, both governmental and private, that such materials should be freely available as an essential resource for plant breeding. The Directive suggests that whoever is able to isolate such identified genes and, by appropriate biotechnological techniques, is able to transfer such genes selectively into an existing variety, will be eligible for patent protection of that gene. Protection covers not just the particular variety, but, from then on, any use of that gene irrespective of its origin. In fact, it will even cover the character itself unless one can prove that another variant of that character is essentially different at the gene level. This proves to be both costly and difficult.

This has a number of potential implications:

1) Patent first and publish later. It will tend to restrict publication of evaluation results to protect the use of such new characters. We may take biotechnologists at their word that identification, sequencing and transfer of genes will become progressively easier.

2) It will, as a consequence, reduce the willingness of genebanks and plant breeders to make evaluated or other materials available. It thereby completely undermines the basic principle of free exchange of genetic resources as agreed upon in the FAO International Undertaking on Plant Genetic Resources, signed by most EEC countries. Countries in still existing centres of diversity of our crops will undoub-

tedly become extremely reluctant to share such resources with others.

3) Plant breeding, by its nature, is a continuous process in which existing cultivars are used as base material for further breeding. This principle is upheld in PBR without restrictions. Patented genes will be fixed in the genetic make up of these cultivars. Even if the plant breeder wants to use the variety for its other characters, incidentally representing 99.999% of more of its DNA, what then will happen? The owner of the gene cannot remove his so-called property. Should he then, because of such inability, be entitled to wield control over the use of such a variety resulting from breeding efforts of countless others going back to landraces?

4) Plants with a patented gene (transgenic plants), when brought to farmers' fields, which certainly must be the objective, may, through natural hybridisation, transfer the gene in question to other materials. These may include other varieties, traditional landraces, even wild relatives. This is not only possible but almost certain to happen. According to the Directive, the patent will still apply to whoever uses the introgressed materials: plant breeders and farmers alike. In fact, if it would not apply, patent protection would be meaningless. How would the holder of a patent disprove a claim of natural transfer? This is to illustrate the absurd consequences that may come from patents on genes in self-replicating organisms.

5) If a specific character is patented at the level of a gene, it will reduce the incentive to search for alternative genetic variants of that character in other material. The patented character will thus tend to be restricted to a single genetic origin, increasing genetic uniformity and thereby increasing the genetic vulnerability of our crops. This may well be one of the most serious consequences and goes directly against all we have learned from past major outbreaks of pests and diseases in some of our major crops.

We see a rather one-sided set of proposals stemming from an industrial research philosophy

These are just only a few examples of the consequences of extending patent protection to genes in plants. I have not discussed issues of double protection, cross licensing, inclusion of dependency clauses and other possibilities to balance the interests of biotechnologists vis-à-vis plant breeders, and so on. A solution should probably be found in establishing a cut-off point for patent protection once a gene is part of a variety or a plant. Plant breeders must then decide whether to follow an often long and costly process of transferring a character into a new variety by traditional crossing techniques, or pay for the services of the owner of a construct containing the gene in question.

Conclusion

Biotechnology has much to contribute; biotechnological research should be justly rewarded. However, I hope I have succeeded in putting forth the notion that the present Directive is perhaps rather biased towards the interests of biotechnological research and perhaps plant breeding in the private sector in an industrial society, at the expense of the wider interests of agriculture and food production as a whole. To put things further in perspective, it is my firm belief that traditional plant breeding will remain the mainstay of crop improvement for some time to come, using biotechnological techniques next to others if and when required. Hence the interests of plant breeding should be safeguarded in any form of legal ownership covering the results of modern biotechnology. This would seem to exclude industrial patents involving living, self-replicating organisms.

THE POSITION OF COPA AND COGECA ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INVENTIONS

Françoise Comte

Original: French

Introduction

I represent here before you two European organisations, COPA and COGECA. COPA, Committee of Professional Agricultural Organisations of the EEC, represents the agricultural producers of the 12 members states to the Community institutions. COGECA, General Committee of Agricultural Cooperatives of the EEC, represents the agricultural cooperatives to the Community institutions. COPA and COGECA defend, therefore, the interests of some 11 million farmers and their cooperatives in the EEC.

Biotechnology is one of the biggest developments at this end of the 20th century. Agriculture is one of the most directly implied sectors as it is essentially a consumer of these products. Biotechnology will bring improvements in techniques and products, both in the animal and plant worlds. That is one of the reasons, in fact, why the Commission's proposal on the Legal Protection of Biotechnological Inventions addresses both animal and plant applications.

COPA and COGECA have taken position on the question of legal protection of biotechnological inventions for what concerns the plant world, that it is to say what appears to us as a suggested solution on the interface of Plant Breeders' Rights, administered by UPOV, and patents. Our position paper, which dates from December 1987, has been made public and circulated. It is still the basis of our thoughts today and I will return to it. COPA and COGECA are in the process of putting together a position paper on (legal protection in) the animal world as well, also affected by biotechnology. Since we have not finished these preparations, I cannot present them to you today.

I would like to divide my talk in two parts:
First a concise presentation of the main arguments of our position;
And secondly our reactions to the proposed Council Directive on the Legal Protection of Biotechnological Inventions, adopted by the EEC Commission in October 1988.

Concise presentation of the our position

Our position is based on two fundamental principles. The first is that plant varieties are subject to specific legal protection in the form of Plant Breeders' Rights in the UPOV system and only this one. These rights, used by agronomists, work fine. We wish them to remain intact.

This principle applies to *all* plant varieties. There is no justification for distinguishing between so-called traditional varieties that are developed through breeding methods known throughout history, and new plant varieties which would be viewed as superior because they incorporate the result of biotechnology research.

For COPA and COGECA, biotechnology inventions have no isolated interest in themselves. On the contrary, it is through their incorporation in a plant variety that they prove their value and industrial usefulness.

The second principle to which COPA and COGECA refer in their position paper is that of *free access.* The UPOV Convention guarantees automatic access to existing varieties for the purposes of varietal experimentation to promote research. Free access must be preserved. It is a basic and primordial rule that allows all researchers to carry out their work successfully.

Varieties subject to breeders' rights

In reality, we are confronting a legal conflict around a single object (the variety) in the case of a biotechnological invention incorporated into a plant variety. The biotech invention has been protected by its inventor. From there, the patentee imposes his rights on the variety over the PBR holder. How do we settle this conflict? COPA and COGECA choose the balanced solution, which does not favour one party over the other, through a system of *licensing.*

If the breeder wants to use the patented invention to select a new variety he must request a license from the patent holder. The payment of a reasonable fee to the patentee will then exhaust the patent holder's rights over the new variety developed by the plant breeder. The patentee will have no right over the product, sale or marketing of the reproductive material of the new variety nor on the subsequent seeds produced by farmers from the purchased seed of this variety.

What must be stressed is the exhaustion of rights of the patent holder. It is this mechanism that will guarantee some form of balance of principles regarding Plant Breeders Rights.

Free access

Here it is a question of relations between breeders, say between initial and secondary breeders.

The secondary breeder will always have free access to the variety for the purpose of varietal creation. He will not have to ask for permission nor pay a fee to the initial breeder: this is the principle of automatic and free access guaranteed by UPOV.

But once the variety held by the initial breeder contains a patented biotechnological invention, and on the condition that this invention is self-reproducible (patented product), the secondary breeder must request a license from the patent holder and pay him a reasonable fee: in this way, both the patent holder's rights and the principle of automatic access are respected. As soon as the secondary breeder hands over the reasonable fee to the patentee, the rights of the latter on the newly created variety are exhausted.

This system will allow multiple breeders which use -- directly or through a plant variety -- biotech inventions, to share the costs. Furthermore, this system would prevent the establishment of monopolies and assure continued improvement of plant varieties.

Reaction to the Commission's proposed Directive

The Commission's proposal establishes a legal regime which separates the field of application of patents from that of Plant Breeders' Rights. This is logical because it is a question of defining respective fields of law for the two domains. The problem is that the proposal takes as a general principle the idea that all living matter is susceptible of being *patented.* Any system of protecting life forms other than the patenting system is treated in the Commission Directive as an exception and, in this view, is the object of very restrictive interpretation. This is certainly the case of plant varieties.

The solutions proposed by the Commission grant special priority to patent law to the detriment of Breeders' Rights

In parallel to this first principle, the proposal foresees mechanisms for extending patents -- that is to say that in cases worded as such by claims, the patent can extend to subject of other forms of protection. In this case, the subject would indeed be patented. This mechanism will apply to plant varieties. In other words, there are cases where plant varieties, being defined as plant varieties in the UPOV sense, will be pulled out of the Plant Breeders' Rights field and end up covered by industrial patents granted to biotechnological inventions incorporated into the variety: plant varieties will be patentable.

The two rules combined -- patentability of life forms as general principle guiding the Directive, and mechanisms for extending the scope of patent protection -- aim, on the one hand, to reduce UPOV's field of application to the utter minimum and, on the other hand, to deny the breeder of his right to PBR protection on a variety containing a biotech invention. I must remind you that our position holds that in no case should a plant variety be excluded from PBR protection. We cannot accept any form of patent extension to plant varieties.

The Commission's position foresees a double mechanism of licensing to govern relations between patent holder and PBR holders. COPA and COGECA hold that this double mechanism is unfavourable to the plant breeder because it is largely biased toward the interests of patent holders. The Directive establishes an imbalance between breeders and patentees by allowing patent holders to have free, immediate and non-monetary access to research material. On the other hand, breeders are subject to a monetarised and delayed access system. In reality, these double mechanisms impose unequal obligations to two parallel situations, and create discrimination again the plant breeder.

We cannot accept any form of patent extension to plant varieties

Finally, the Commission's proposal foresees the reversal of the burden of proof. Unless proven otherwise, a product is deemed to have been obtained through a patented process. This rule will force breeders of varieties containing patented biotech inventions into a very difficult situation, especially with regard to patent extension mechanisms already spelled out in the Directive.

Conclusion

The solutions proposed by the Commission grant special priority to patent law to the detriment of Breeders' Rights. The framework reserved for Breeders' Rights (within the Directive) opens the door to the extinction of the independent breeder in the circuit of new inventions through the takeover of breeders by big industry, or at least a major drop in the remuneration granted to breeders for their work in improving plant varieties.

This is intolerable to the extent that agricultural cooperatives, which are the economic bodies directly managed by farmers, would like to take up biotechnology research and would now find themselves facing a market monopolised by a couple of big industrial firms specialised in biotech research. COPA and COGECA wish, on the contrary, that the interests of all parties concerned -- agricultural producers, agricultural cooperatives, big industry -- be taken into account.

It is in the public's interest to protect the farmer and to avoid making him dependent on a couple of big monopolies. The monopolisation of the market will raise seed prices, which is intolerable in a period of permanent restrictions on revenue in the current framework of reform of the Community Agricultural Policy. Finally, research concentrated in the hands of a couple of large industrial groups will not be active. It is competition that promotes the invention of better products.

A balanced system between Breeders' Rights and patents, preserving the rights and interests of all parties concerned,

would best contribute to the creation of high-quality plant varieties in the future.

The Commission's method of working to prepare this Directive did not allow all interested parties to participate in a true dialogue. COPA and COGECA note that most of the solutions adopted by the Commission in its proposal are those proposed by WIPO, the World Intellectual Property Office, which in preparing its 1987 study on the matter consulted organisations that only represented the interests of industry. To us it is regrettable that the Commission did not consult all interested parties connected to this question.

We would have also preferred that the projects carried out within the Commission, one related to the legal protection of biotechnological inventions (DG-III) and the other to the creation of a Community Breeders' Right (DG-VI), had been done in harmony, given that they both deal with the problem of interface between legal concepts.

It is regrettable that the Commission did not consult all interested parties connected to this question

As I said in my introduction, biotechnology poses a great challenge for the end of this century. The Commission itself announced the importance of promoting the food industry within the framework of the reforms of the CAP. We are not convinced that the Commission has taken the right direction.

We hope that the Council of Ministers will take the right decisions.

PATENTING LIFE FORMS: THE IMPACT ON FARMERS

Gérard Choplin

Original: French

I represent the European Farmers' Coordination, a group of 12 organisations from 7 European countries not represented by COPA. I think that it would be difficult for COPA to represent 11 million farmers, as said before, because I do not think we have 11 million farmers left. We try to do our best for the continued survival of at least a few million farmers because the sector is slimming considerably and we need therefore also to look at the patenting and at the deliberate release of genetically modified organisms, which could lead to the further slimming of this sector.

Let us be frank and realistic. I think this is very important if we want, objectively and democratically, to talk on behalf of farmers. There is very little discussion among farmers on the patentability of living material or on micro-organisms. There are more and more articles, I agree, in the farming press but there is not much discussion among farmers themselves. I will restrict myself here to one or two questions which I think are important and I would like to leave a great deal of time for discussions.

There is very little discussion among farmers on the patentability of living material

I think this is a useful opportunity for gathering information and developing discussion but I think it is important that there be a broad public discussion on this issue before any decision is taken. As Madame Hermitte said in an article in *Le Monde Diplomatique* of last December, there is a massive change in the legal habits of the industry. It is of a kind perhaps unprecedented in Europe and it seems urgent to us that the EEC should wait before it takes a decision. The discussion though should not just lie with eurocrats or technologists but I think it is of interest to all human beings -- farmers or otherwise -- and it is not just a legal discussion, as people perhaps wrongly think. It is an ethical, economic, social and political discussion.

In view of ethics, do we want to consider micro-organisms, plants, animals and so on, as objects which can be owned? It is a question that needs to be discussed. Personally, I would give a resounding no. But what is important is that before any decision is made at the Community level, we need to discuss this via all the different media. Now so far there has not been any discussion, as far as I am aware. Even though COPA may have a view, in the French countryside and in the local organisations there has not been any discussion of this and I think it is very important for this question, which is of interest to every human being, to be approached democratically and properly. We are criticising the Commission for twisting peoples arms and taking decisions without discussion, and we must avoid falling into the same trap. We need to have a broad-based democratic discussion.

Another point is that in our view, the Commission has been assuming that the EEC is primarily an economic organisation and I wonder whether an economic organisation is the right forum to deal with a profound ethical problem. Would it not be best to set up a European Ethical Committee which would be politically and economically independent, and which could make proposals on these essential ethical questions? There are (bio-)ethics committees in some European countries -- could there not be a European-wide one which would escape much of the lobbying which is currently brought to bear on the Commission?

Politically, the question is whether we consider farming as an industry, a point many people referred to this morning. I think that few people at the European level have come out clearly on either side of this argument so far. To say that farming is an industry, I think, would immediately condemn perhaps up to 5 million farmers in Europe to disappear from the face of the earth. If we wish to justify the extension of patents along industrial lines to agriculture, then I suppose we have to accept that farming is an industry and micro-organisms, plants and animals and so on can therefore be owned by private commercial interests. So it is a political discussion: should we allow industry to control an increasing number of food production processes? Should we allow industry to provide increasingly cheap raw materials for food production?

Economically and socially, in very concrete terms for farmers, if the farmer is obliged to pay additional duties when he wants to sow seeds which he himself has harvested well, obviously then, this will involve new production costs -- who will pay them?

This will involve new production costs -- who will pay them?

Let me give an example. Say a super wheat is developed through genetic engineering. Imagine it is a nitrogen-fixing strain of wheat, resistant to four or five herbicides, also resistant to insects, it absorbs all the things to which it is subject without damage and it also puts into the atmosphere the kind of things we need at present. If royalties have to be paid on all these properties of the super-wheat, how much will it cost and who will pay?

At the level of production costs, when farmers' organisations ask for farm prices to be increased, along the lines of different formulae, there is always a great outcry because people say this will increase food prices. Even though it does not account for a great proportion of the overall price of milk or yoghurt. But if the Commission comes along and says, *Well, here is a proposal which will increase costs to the farmer,* there does not seem to be the same outcry because there is not a widespread realisation that it will bring about an increase in costs at the consumer level at well. I do not know whether it is a point which has been properly understood. I wonder if the assumption is that the farmer will have to pay. Because people go to the authorities who go to the farmer and say: Bring down your production costs! It may seem odd therefore that the Commission is proposing a Directive of this kind now, whereas elsewhere, it continues to ask farmers to reduce their production costs so as to adapt to price falls.

This means that there will be further intensification, which is another contradiction in the Commission's approach

Now of course with the existing price system, I think I agree with my colleague from COPA on this, farmers are obliged to use all the new varieties which are on sale. They are super efficient, they may carry 10 or 15 patents, and farmers are obliged to use them. They are increasingly dependent on use of hybrids for the seeds, and they are increasingly dependent on industrialists. And this means that there will be further intensification, which is another contradiction in the Commission's approach. In such texts as *The Future of Rural Society*, the Commission proposes measures for extensification, and here it seems they are proposing a measure which will work in the opposite direction and bring about further intensification.

As to optimise the costs, as has been said this morning, industrialists may market only a small number of patented varieties because, of course, they do not want to develop too many of them and the risk is increased that, apart from the question of genetic erosion which is serious, there are considerable risks in that some industries will have increasing control over our choice of food which will be more and more restricted. Should we then condemn farmers to increased dependence on industrialists? Should we also condemn consumers to an increasingly restricted choice in what they eat?

PLANT GENETIC RESOURCES: PROTECTION OF RIGHTS

Jean-Pierre Chiaradia Bousquet

Original: French

The first debates on the subject of plant genetic resources that arose within the United Nations Food and Agriculture Organisation (FAO) started in 1947. Since 1957, a news bulletin on the subject is published regularly by FAO.

In 1961, an international meeting was held, leading to the creation, in 1965, of an expert committee on plant production and introduction, whose mandate was to advise FAO and establish international guidelines on collection, conservation and exchange of plant germplasm. As well, in 1968, a Crop Ecology and Plant Genetic Resources Unit was formed with a mandate to organise and promote activities related to safeguarding and utilising plant genetic resources. Furthermore, FAO participated in launching the International Board for Plant Genetic Resources (IBPGR) which it houses and lends support to. IBPGR is an autonomous, technical non-governmental body created in 1974, administered by the Consultative Group on International Agricultural Research (CGIAR).

This special attention always granted by FAO to the field of plant genetic resources is justified as much by legal concerns of FAO as by geo-economical considerations.

It is well know that the majority of the world's plant genetic resources are found in the tropical and sub-tropical zones rich in plant species, and that these zones often correspond to territories of developing countries, poor in financial resources and technical personnel. It appears that the socio-economic potential of plant genetic resources can be fully exploited if they are available and accessible; they must be utilised and are fully utilised for varietal improvement in breeding programmes employing appropriate technologies including the new biotechnologies. In this view, the international community must help support national programmes designed to conserve germplasm, breed improved varieties and adapt biotechnologies to the needs of the developing countries.

The global FAO system on plant genetic resources

Although numerous discussions and studies on technical and economic aspects of plant genetic resources were carried out in the 1960s and 1970s, it is especially since 1979 that major debates on the interaction between technical, legal, economic, social and political questions related to plant genetic resources emerged at FAO. Resulting from these debates it appeared that conservation of these resources and the critical principle of free access to them would be threatened if a fair world system -- permitting germplasm donor and recipient countries to benefit equitably from utilisation of these resources -- was not set up.

It was therefore on request of its Memberstates in 1983 that FAO established a world coordination and action system in the field of plant genetic resources. This system, founded on FAO's longstanding experience in this area and within the framework of the Organisation's mandate, is composed of the following elements: (1) a legal framework, *viz* the International Undertaking on Plant Genetic Resources; (2) an international forum, the Commission on Plant Genetic Resources; and (3) a financial mechanism, the International Fund for Plant Genetic Resources.

Under Article 7 of the International Undertaking, certain additional support elements are called for including an international network of base collections under the auspices of FAO, a global information system on plant genetic resources conserved in these base collections, and an alert system in case of threats to the safeguarding of this conserved material.

The International Undertaking was adopted by the FAO Conference in 1983

The International Undertaking on Plant Genetic Resources (Resolution adopted during the 1983 FAO Conference) is a flexible legal instrument based on the recognised principle according to which plant genetic resources are the common heritage of mankind and must be preserved and maintained freely available for scientific research and plant improvement.

The Undertaking's objective is to guarantee collection, conservation, maintenance, evaluation and unrestricted exchange of plant genetic resources, especially those that carry special social and economic value for the present and the future, for use in crossing and other scientific applications.

Furthermore, Article 4 stipulates that legal and other measures will continue to be applied and, where needed, new measures will have to be elaborated to protect and preserve plant genetic resources of species growing in their natural habitat in the principal centres of genetic diversity.

International cooperation should, in this framework, particularly favour the establishment or strengthening of the capacities of the developing countries, where necessary on a national or sub-regional basis, in activities regarding plant genetic resources, notably inventories, identification and plant breeding, seed multiplication and distribution; the aim is to allow all countries to benefit fully from plant genetic resources in the interest of agricultural development.

Article 7 specifies that the material contained in the base collection established in the framework of the Undertaking is at the free disposal of signatory parties on the basis of mutual exchange or according to conditions fixed through common agreement.

The second element of the FAO system, the Commission on Plant Genetic Resources, was created upon request of the 1983 FAO Conference. This is the only world forum permitting all countries -- including donors and recipients of plant germplasm, of financial aid or of technologies for exploiting plant genetic resources -- to monitor the implementation of the principles laid out on the International Undertaking. During its debates, the Commission strives to arrive at a consensus on questions of global interest and reach a compromise on the subject where divergences appear.

The meetings of the Commission also allow to coordinate activities and agree on responsibilities. Apart from Memberstates of the Organisation, certain technical assistance bodies, lending agencies, development banks and diverse non-governmental organisations participate in these sessions.

The daily and constant labour of farmers in conserving and improving germplasm calls for attention and recognition

As another element of the FAO system, the International Fund was created in 1987. It aims to promote the conservation of plant genetic resources and encourage their utilisation. The Fund can also be considered as a compensation mechanism for donors of this material, in recognising their contribution to the progress of world agriculture, thanks to the efforts carried out by farmers over countless generations to conserve, improve and make available this essential plant genetic material. Numerous governments, non-governmental or intergovernmental organisations, as well as private foundations have already contributed to this Fund. Private enterprises have also been invited to participate in this effort.

Today, 117 countries have become members of the Commission (93) and/or signed the Undertaking (84). This FAO system -- International Undertaking, Commission and Fund -- is directed to the conservation and utilisation of biological diversity in genes, genotypes, plant genepools at the molecular level of species and/or ecosystems, both *ex situ* and *in situ*.

It is worthwhile to come back a moment to the fundamental principles of the Undertaking in order to understand the basis of today's debate.

Towards a common interpretation of the Undertaking

The International Undertaking was adopted by the FAO Conference in 1983. Since then, 84 states, of which a nonmemberstate of our Organisation, have signed. Fifty-seven of them joined unconditionally, while the other 27 have expressed reservations.

Four states have specified the reasons of their not signing: possibility of conflict between obligations of international law arising from the Undertaking and their national legislation regarding Plant Breeders' Rights. During its second meeting in 1987, the Commission nonetheless recognised that if, in certain respects, the Undertaking may cause some legal problems in certain countries, Plant Breeders' Rights are legitimate rights and do not necessarily impede access to protected varieties for research and the creation of new material.

On the other hand, certain states, generally developing countries, have expressed their reservations on the Undertaking because free access to plant genetic resources would be contrary to the interests of national sovereignty or to the protection of certain species of particular economic importance for the country.

During this same session (March 1987) of the Commission on Plant Genetic Resources, the important role that farmers traditionally play was stressed, as much in their activities in enhancing as in conserving plant genetic resources. The work accomplished over centuries and continuing still today, the daily and constant labour of farmers in conserving and improving germplasm calls for attention and recognition because it has resulted in the creation of very diverse plant types that are the prime source of genetic variability. The concept of Farmers' Rights was established from this observation: many delegations felt that these rights were to a certain extent comparable to Plant Breeders' Rights which have been recognised in certain national legislations for several years. They therefore recommended that the rights of farmers also be recognised by the international community. In this respect, it was stressed that the International Fund could offer the means to compensate the input of agricultural communities through support for improved conservation and enhancement of plant genetic resources for the benefit of farmers in developing countries; in this respect, the development of biotechnologies that respond to their needs and capacities is fundamental.

Neither international nor national law recognise yet this new concept of Farmers' Rights

The reservations expressed regarding the Undertaking were directed toward the conflict between the fundamental principles of free access to plant genetic resources as stipulated in Articles 1 through 5, and the very definition of plant genetic resources which includes:

i) cultivated varieties (cultivars) in current use and newly developed varieties;
ii) obsolete cultivars;
iii) primitive cultivars (landraces);
iv) wild and weed species, near relatives of cultivated varieties;
v) special genetic stocks (advanced breeders' lines, elite material and mutants).

In certain Memberstates, cultivars are protected by Plant Breeders' Rights; most of these countries are also members of the International Union for the Protection of New Varieties of Plants (UPOV) whose objective is to defend Plant Breeders' Rights.

It therefore appeared necessary to reconsider the Undertaking's terms within a common interpretation that could take into account the parallel recognition of the rights of breeders and those of farmers. For most delegations to the Commission, these rights derive from the daily efforts of farmers, efforts which have given rise to the creation or breeding of very diversified plant types that are the main source of genetic variability. It should also be noted that many of these resources are exploited in countries other than those where they originated.

In the search for an commonly acceptable interpretation of the Undertaking, three concepts are at the centre of discussion: the notion of common heritage of mankind, Plant Breeders' Rights, and Farmers' Rights.

The first point of discussion: common heritage

The concept of common heritage in the strict sense can only be applied in part to the field of plant genetic resources because, among other things, these resources are generally subject to national law of sovereignty. The notion of common heritage was nevertheless already invoked under the auspices of the General Conference of UNESCO (United Nations Educational, Scientific and Cultural Organisation) which in 1972 adopted the Convention concerning the protection of the world's cultural and natural heritage. Known as the World Heritage Convention, it covers cultural and/or natural goods subject to national sovereignty. The introduction of the notion of common heritage or world heritage is a means of transcending political and geographical borders.

The concept of common heritage is characterised by five principal elements:

1. free space cannot belong to anyone;
2. all peoples have a right in the utilisation of resources which must be managed by a single system;
3. the economic benefits arising from the exploitation of natural resources must be shared equitably;
4. these resources must only be exploited toward peaceful ends;
5. scientific research must be free and open to all as a concern for protection of the environment.

The essential principles of the notion of common heritage of mankind should therefore be retained: regarding plant genetic resources their conservation and exploitation must be carried out in the spirit of cooperation for the common benefit of all nations, be it on a free basis or in the framework of negotiated agreements.

Scientific research must be free and open to all as a concern for protection of the environment

Second point of discussion: Plant Breeders' Rights

Recognition of Plant Breeders' Rights is the outcome of technological developments in plant breeding. Different legal instruments conferring recognition and defense of these rights already exist in certain developed countries. As well, the Convention establishing the International Union for the Protection of New Varieties of Plants (UPOV) was adopted in 1961 with the objective of defending Plant Breeders' Rights within the territory of memberstates as well as on the international level.

The fundamental criteria for the recognition of these rights are that the plant varieties in question be different from other existing varieties, stable, uniform and homogenous.

One of the effects of this form of protection is that commercial scale production and marketing of the propagating material of the variety requires the consent of the breeder, who can impose conditions on the use of his variety.

There are certain limits here, one of them being that the protected variety can otherwise be freely used for the creation and marketing of another new variety.

In certain countries, such varietal rights are directly linked to legislation on intellectual property, be it industrial or commercial, or patent laws. In these cases, the protection conferred is much stricter. The holder of such rights can impose greater restrictions on the potential use of the registered variety.

Third point of discussion: Farmers' Rights

Neither international nor national law recognise yet this new concept of Farmers' Rights in a complementary manner to Plant Breeders' Rights, as was proposed, defended and elaborated on by numerous FAO Memberstates during the second session of the Commission on Plant Genetic Resources.

To be sure, farmers hold property or users rights over plants which grow in a territory they have some form of title over. Up until now, however, these rights do not cover species, not even varieties *per se*.

This new right is based on the recognition of the enormous contribution of generations of farmers, immense efforts which were carried out for over ten thousand years in the areas of conservation, breeding, domestication, development of plant genetic resources and also knowledge -- empirical but fundamental -- of these resources.

Breeders use these varieties whose mutations have been furthered over centuries by farmers and are granted rights and titles of compensation for their efforts. Why should it not be so for the farmers who are the natural inheritors of past generations and are also the current actors in such developments? Breeders and farmers participate in this development at different but undeniable degrees, all of them using knowledge and investment.

Patent legislation makes it illegal for farmers to use re-use seed harvested from plants containing patented material

The new concept is still difficult to define in legal terms due to the fact, among others, that primitive cultivars developed by farmers are heterogeneous and instable, which makes identification difficult. Another shadow zone results from the fact that cultivated species are rarely confined to their habitat of origin and borders are not intangible. The subjects of these new rights are not individually identifiable.

Nevertheless, the Commission felt that the recognition of Farmers' Rights should be directly connected to the establishment of the International Fund for Plant Genetic Resources, established in the framework of Article 8 of the Undertaking. As a form of compensation, the contributions to the Fund can provide the means to establish national programmes for germplasm conservation and varietal improvement, particularly through the use of the powerful new tools of biotechnology. It is important to outstrip rigidities and make an appeal to the participation of everyone in order to avoid divisions and conflict of interests so we can arrive at a global solution.

These three preceding points of discussion show the way to an eventually harmonised interpretation of the Undertaking, which could be followed by the search for agreement among the different positions expressed at the second session of the Commission on Plant Genetic Resources.

But new difficulties may arise in another field: the rapid evolution of new biotechnologies and the adaptation of law to them. A classic issue which takes on a new character today.

The emergence of new biotechnologies

From a legal point of view, the emergence of the new biotechnologies could have a sizable impact on the system of Plant Breeders' Rights because the results of these new techniques call for a more rigid form of protection, particularly through industrial patenting. Breeders who use gene transfer and similar techniques have an interest in securing strong legal protection over genes and gene complexes rather than on the plant varieties obtained. In order to provide such protection, the notion of industrial patenting has been extended to plants and even animals in certain industrialised countries. This more restrictive legal regime confers the legal principle of property rights over single genes, gene complexes, genetic characteristics and specific processes used for the production of new plant varieties.

In contradiction with the now classic system of Plant Breeders' Rights, the granting of industrial patents blocks breeders from freely using the multitude of plant varieties because the germplasm contained in those varieties is the subject of exclusive property rights. In order to use patented processes or products, breeders must request a license from the patent holder. In certain countries, the patentee is free to refuse the grant of such a license.

Patent legislation also makes it illegal for farmers to use re-use seed harvested from plants containing patented material.

It is clear that patent law applied to plant material will have an unfortunate impact on the principles laid out in the International Undertaking, especially that concerning unrestricted free access. If patenting genetic material or genetic characteristics becomes common practice in the industrialised countries, a part of the germplasm found in the different categories of plant genetic resources described in Article 2.1(a) of the International Undertaking will become subject to private property.

Because of the increasing economic potential of plant genetic resources, including special genetic stocks, numerous industrialised countries will refuse to accept that they be considered as the common heritage of mankind and, therefore, freely exchangeable.

Patent law applied to plant material will have an unfortunate impact on the International Undertaking

It is in this sense that the new biotechnologies will make it more difficult for certain countries to accept the principles spelled out in Articles 1, 2.1(a)(v) and 5 of the International Undertaking.

It remains to be seen whether the new biotechnologies will change the context of global germplasm exchange to the extent that amendments to the Undertaking will be necessary. This does not seem to be the case at present because the Undertaking states that exchange of plant genetic resources should be open and without restriction. An accepted interpretation of certain articles should be a sufficient response to the new situation.

Another question arises when we look at Article 2.1, which defines what is understood by plant genetic resources. This definition covers genes derived from non-cultivated plants (even micro-organisms) which will take on greater importance through the development of new technologies. This article defines plant genetic resources as being the reproductive or vegetative propagating material of the following categories of plants: (a) cultivated varieties (cultivars) in current use and newly developed varieties; (b) obsolete cultivars; (c) primitive cultivars (landraces); (d) wild and weed species, near relatives of cultivated varieties; (e) special genetic stocks (advanced and elite breeding lines and mutants). It does not specifically cover genetic material of non-traditional plant species whose genetic makeup is growing more important for plant breeding through new technologies. Nevertheless, Article 2.2, which stipulates that the Undertaking covers *the plant genetic resources of all species of economic and/or social interest, particularly for agriculture at present or in the future, and has particular reference to food crops,* appears broad enough to cover non-traditional species.

Furthermore, it must be noted that the new technologies are increasingly allowing non-plant genes to be incorporated into plants, and these do not appear to be covered by the Undertaking.

The rapid development of new biotechnologies also has repercussions on the International Undertaking regarding the international arrangements laid out in Article 7. Such is the case regarding the international network of base collections in genebanks (Art. 7.1(a)) which also covers *in vitro* germplasm collections and DNA libraries. The global information system, referred to in Article 7.1(e), must also take account of and diffuse information on the development on new biotechnologies themselves. The early warning system must also apply in the case of risks that arise following the release of genetically-modified plants and micro-organisms into the environment. It is necessary to devise systems that will allow the developing countries to adopt and develop biotechnologies for their own particular benefit.

What is certain is that biotechnology will be primarily used in the developed countries

With the development of transgenic plants and micro-organisms, many questions regarding legal control over testing and deliberate release into the environment have been raised. Controversies over this have broken out in several countries. It has been suggested that the Undertaking's Article 10, which covers plants protection measures, be interpreted in such a way as to cover release of transgenic plants and micro-organisms.

The new biotechnologies are powerful tools which may be used to serve different goals. They hold considerable promise of greater efficiency in conservation and utilisation of plant genetic resources, thereby facilitating the implementation of the principles laid out in the International Undertaking and the achievement of its goals. The effects of these new technologies on agricultural production and trade are still, in any event, totally uncertain.

What is certain, though, is that biotechnology will be primarily used in the developed countries. The international community must somehow concentrate its efforts on the development of certain biotechniques so that tropical crops and small-scale farmers may benefit from them.

From all this it is obvious that the new biotechnologies will raise a certain number of questions regarding their legal, social, economic and political impacts. To be sure, these questions could be dealt with through an agreed interpretation of certain articles of the International Undertaking.

PATENTING OF ANIMALS: A WELFARE VIEWPOINT

Joyce D'Silva

Original: English

Humankind has been exploiting animals for hundreds of thousands of years. Humans have also exploited other weaker or poorer humans. Alongside both kinds of exploitation there have always been those who fought against it -- those who questioned the philosophical, theological, social, economic or cultural reasoning which was used to justify the exploitation.

In the Western world we have come to recognise -- officially if not in practice -- that all humans have basic rights. Some have extended the concept of rights to animals. Many have come to view the whole planet as a living interdependent ecosystem in which we all participate and in which each species of living matter has its place, or at least is entitled to its place. Could it be that this growing awareness is part of our evolution -- not of our bodies -- but of our psyche?

What has happened to our ethics?

Sadly, alongside this extension of the circle of our sensitivity, there is still a strong exploitative streak in our society. Those who adhere to this view see animals solely as utilitarian objects. Some, busy making their fortunes from vivisection, factory farming or the fur trade, even deny that animals can feel pain, can suffer. This attitude can be revealed in phrases like the LD 50 Test -- an innocuous sounding name for a test which involves feeding poisonous substances to a group of experimental animals until 50% of them die. On such hidden and indeed often inaccurate horrors do we base our human safety regulations. We see farm animals in terms of stocking densities, minimum space allowances, feed conversion ratios, productivity, mortality rate, fertility, reproductive capacity and carcass weight. In so doing, do we fail to see the living, feeling, sensitive creatures behind the statistics?

At the end of this narrow and ruthless path we now have a final draft of the EC Directive on the Legal Protection of Biotechnological Inventions -- a Directive which will allow for the first time in the EC the patenting of genetically manipulated animals. This must surely by the ultimate expression of anthropocentricity.

For thousands of years our ancestors believed that the stars and sun revolved around the earth. This Directive is surely proof that the EC Commission believes that the world of living organisms revolves around humankind.

The narrowness of thinking behind the Directive is exemplified in the Explanatory Memorandum to Article 2 which states quite openly *there is no reason to exclude from protection (i.e. patent protection) inventive activity relating to living matter, other than the area of humankind.* Interestingly, Article 2 itself makes no mention of human exclusion, leaving the way open for patenting of animals containing human genetic material.

There are other revealing phrases in the Explanatory Memorandum giving the reasoning behind this Directive *to foster the overall innovatory potential and competitiveness of Community science and industry, to keep pace with the leading nations,* to *secure costly investment in research and development and industrial exploitation of research results.*

And what kind of research will be relevant to the patenting of animals? There will be a massive increase in vivisection as new and more efficient techniques of gene splicing, gene insertion, cloning, etc. are tried out on a variety of animals. With a failure rate of 75% for foreign gene insertion in mice, thousands of animals will be discarded. Those carrying the inserted gene will be patented as Cancer Mouse, AIDS Mouse, etc. This is no far-fetched scenario. The first creature patented in the U.S. last year was indeed a mouse with an oncogene inserted to predispose it to cancer. A creature developed in the certain knowledge of its future suffering pain. A patent which, in my opinion, debases not only the patented animal itself, but also its creators at Harvard University, its patent holder DuPont, its users, and those who granted the patent on it, the U.S. Patent Office.

Not only will thousands of animals suffer and die of necessity in the course of such work, but the state of knowledge of genetic manipulation of animals is so limited that thousands of abnormal creatures will be developed -- creatures like the pig with the human growth gene developed at the U.S. Government Research Center at Beltsville. This pig did indeed achieve the leaner carcass which was the object of the exercise -- however it had a deformed skull, defective vision, was arthritic, lethargic and impotent. Its short life was surely better not lived. One researcher admits that *a high degree of sterility and other physiological problems associated with gene expression are relatively well known*[1] and another has said, *Not only do we not know which genes to transfer, we do not yet have a strategy for identifying most of them effectively.*[2]

A patenting Directive which debases animals to the level of inanimate objects deserves no place in Community legislation

The transgenic animals may carry their patent protection, but that is all the protection they will get. A whole new range of health problems is likely as a result of the genetic manipulation itself. And the types of manipulation, such as clo-

ning on a vast scale, will lead to a massive susceptibility to just one disease strain. A disease epidemic in a herd of cloned animals will be far more devastating than in an ordinary herd where some animals will resist infection due to their varying genetic inheritance or health status. No such natural protection will be available in cloned animals.

The Directive will not only allow to patent genetically engineered animals themselves, but also the processes and techniques by which they are engineered. As the Explanatory Memorandum to Article 18 states, it will allow the patenting of surgical processes used in breeding, such as multiple ovulation, embryo recovery and transfer, and processes for improving feed conversion ratios such as surgical implantation of growth stimulating or regulating substances.

Interestingly, you will not be able to patent a surgical techniques undertaken for therapeutic purposes -- but only one which is capable of industrial application. You cannot patent a technique to cure a defect, but you can patent an inherently mutilated animal and the mutilating process, if there is profit at the end of the day.

What kind of patents could we see? There is serious talk of *splicing genes from mice into pigs to produce sows that could give birth to 25 piglets, more than double the average litter today*[1], talk of *a dairy cow the size of an elephant and capable of producing 45,000 lbs. of milk a year*[4] -- over twice the amount produced by today's high-yielding cow, making BST seem like a very primitive step in the mighty ladder of biotechnological development.

We could see a patent on a technique of producing tetraparental chimeras -- cattle formed by fusing the embryo of a normal cow with an embryo from a double-muscled cow such as Charolais or Belgian Blue. As R.B. Church of Calgary University says, *the double muscling trait is desirable because it offers the economic advantage of producing veal-type meat (due to muscle hyperplasia) on 350 kg mature animals rather than 90 kg calves.*[5] He admits the drawbacks: *It gives rise to extraordinary foetal growth (the animal is approximately 65 kg at parturition compared with 40 kg normally and must be born by Caesarian section); the calves require intensive nursing to reach maturity and the animal is reproductively unfit.*[6]

The transgenic animals may carry their patent protection, but that is all the protection they will get

What has happened to our ethics? When I read statements from biotechnology researchers such as: *transgenic animals can also be viewed as production systems for useful peptides*[7], or: *new animals ought to be patentable for the same reason that robots ought to be patentable: because they are both products of human ingenuity*[8], I am worried. I note that the U.S. Commissioner of Patents, Donald Quigg, said in reference to the first patented mouse -- Cancer Mouse -- *How can anybody say that this kind of development is unethical or wrong?*

I believe that it is unethical -- profoundly so. Animals should not be viewed only from the point of view of human usefulness and profit. They are creatures whose genetic material is so similar to our own that it can be transferred from one to the other. They share our five senses. They share our nervous system and thereby our ability to experience pain. But they lack one human advantage: whilst we can rationalise our pain and anticipate its end, they cannot -- they must simply endure it. For this reason most of all, they call on our respect, our care and consideration.

Humankind does not have an inherent monopoly on this earth. We have simply developed a temporary technological dictatorship. We have, after all, already built the weapons with which to destroy ourselves. We are beginning to realise that our concentration on physical and mental power has led to a limitation of our sensitivity to the earth on which we live and the needs of other people and creatures who share it with us.

A Patenting Directive which debases animals to the level of inanimate objects and which will provide a massive incentive to experimentation by the biotechnology companies and agribusiness multinationals, and which will profit only the already rich and the already powerful, deserves no place in Community legislation. I would suggest that this Directive is out of step with the feeling of the times in that it reflects most of all the attitudes of that well known medievalist Thomas Aquinas, who stated clearly, *By divine providence, animals are intended for man's use.* As such, it represents the nadir of humanity's psychological evolution

NOTES

(1) Embryo Manipulation and Gene Transfer of Domestic Animals, R.B. Church, University of Calgary, published in *Tibtech,* January 1987, Volume 5.

(2) New Opportunities in Animal Biotechnology, the late Professor Roger Land, AFRC Institute of Animal Physiology and Genetics Research, Edinburgh, published in *Science and Change in Agriculture,* AFRC 1988.

(3) U.S. Acts to Allow Patents on New Animal Forms, Keith Schneider, *International Herald Tribune,* 8-2-1988.

(4) *Business Week,* 1982.

(5) R.B. Church, *ibid.*

(6) R.B. Church, *ibid.*

(7) R.B. Church, *ibid.*

(8) A Science Court, Roger Schank, Professor of Computer Science and Psychology, Yale University, published OMNI January 1988.

(9) Donald Quigg, *New York Times,* 13-4-1988.

SOME THEOLOGICAL AND ETHICAL POINTS OF CONCERN ON THE ISSUE OF THE PATENTING OF GENETICALLY ENGINEERED LIVING ORGANISMS

Reverend Dr. F. Rajotte

Original: English

Introduction

I would like to thank ICDA for organising this conference because the issues raised have been of great concern to the member churches of the World Council of Churches.

We have at the moment some 306 member churches so it is with some fear and trepidation that I say anything at all. First of all what I do want to say is not in opposition to genetic engineering *per se*. It is recognised that there are very important medical, environmental and agricultural advances to be made.

There are nevertheless concerns that have already been raised that are very great concerns to the members of the World Council of Churches: concerns about the diversity of both the natural and domesticated environment, the diversity of species, concerns that have been raised about agriculture, about the abuse of animals. At a recent conference we held in September, a fairly lengthy statement was made by an ecumenical group of churches on animal rights. I will focus my own remarks here on the theological and ethical issues around patenting life forms.

While most Christians acknowledge that genetic engineering technology can result in important medical and agricultural advances, and possibly to environmentally beneficial products, the concept of regarding living entities as objects of human invention is not acceptable. It would require a radical denial of value systems and an unacceptable shift in moral ethics.

To claim a patent on a life form is a direct and total denial of God

The extension of intellectual property rights to living beings reflects the brokenness of the relationship between humans and the rest of creation -- a brokenness that, if not challenged and reversed, will lead to the destruction of both, for *each new power won by man is a power over man as well* (C.S. Lewis, 1965).

The very word creation implies that there is no owner of the planet, with all that lives upon it, except for the living God. To claim to patent on a life form is a direct and total denial of God as creator, sustainer, breath of life, immanent spirit in the within of all being.

The Earth is the Lord's, is a statement of value. Each life belongs to the subjectivity of itself. Each and every organism has its own subjective within, and fulfills its own being in relationship to all other beings in the biosphere, and to God its creator.

Christians today are reaffirming that life, *all* life, has value, that each and every life, part of the interrelated and holistic biosphere, the atmosphere, land and sea, is to be revered, cherished and cared for, and that it reflects the immanence of divine creative love in and for the world. The incarnation and the life, suffering and crucifixion of Christ reveal the depth of divine love in and for the world.

Life as value challenges the drive to patent

The view of every living creature as of value to God challenges several major paradigms that underlie the demand to patent life forms.

1) It challenges the dualistic view that there can be separation between science and religion, between the material and the spiritual.

2) It opposes the attitude that regards the entire planet as merely a resource for the taking, and regards atmosphere, forests and sea as free goods, to appropriate, pollute and discard. As industrial expansion pushes against global limits, the only area still available for expansion is that of life itself -- to appropriate and own the essential subjective being of the biosphere. It is the ultimate extension of the imperialist movement of capital to acquire and control the global goods.

3) What is wrong with the patenting of higher animals is (more than simply the suffering that is caused by experimentation and confinement) the fundamental wrong of viewing animals as purely instrumental, as only objects and resources existing for our exploitation and as of having no value in and for themselves, and as being of no value to God.

4) The understanding of faith finds totally inadequate the mechanistic paradigm that views life as merely assemblages of molecules programmed by self-replicators. This is reductionist to the extreme and does not do justice to the insights of science itself or to human experience.

5) We live in a holistic and interrelated world where we are increasingly responsible for the consequences of our ac-

tions upon all the rest of the living biosphere. There is no such thing as an objective, neutral observer. We only exist as subjective beings in relationship to other subjective beings. We are what we observe.

6) To claim living organisms as human creations and intellectual property is to radically change and devalue our entire attitude of wonder, reverence, respect for life, compassion and love (which form the basis of moral and ethical action) and replace it by ownership, control, power, competition and dominance.

7) As churches have recently spoken out against racism and sexism, so within the context of the present debate on Justice, Peace and Integrity of Creation, they have repeatedly opposed anthropocentrism and specieism.

The life of the world is not a raw material input of consumer production

8) Present paradigms of development have not only failed to eradicate want and poverty, but have increased the profits and power of the wealthy at the expense of the powerless. In today's small global village it is essential to focus upon a distributive ethic based upon human need and concern with global welfare and justice. Development workers see patenting as being a step toward market control. They are also concerned with the maintenance of genetic diversity.

9) Today, knowledge and technological ability are power. This new, vast power of genetic engineering should not become exclusive property used to further enrich an élite corporate minority that already has vast economic power, and associated military interests (in conventional, nuclear and chemical weapons). Corporate vested interests may not be in the best interests of humanity. Hugh Iltis cites the example of an Andean Peruvian tomato sample no. 832, which he estimates cost the U.S. government only $21 and which happened to have the characteristics commercial growers were seeking. He estimated, *The value to the tomato industry of the genes found in collection no. 832 could, if widely incorporated, be worth about $8 million a year!* Is this just? Is it not again using technology to pillage the genetic resources of the Third World in order to further concentrate profits and competitive advantage? There is total agreement that in following Christ's teaching, churches are in solidarity with the poor.

10) New knowledge dependent on thousands of years of cumulative human development, culture, education and research should rightly be the property of all.

11) In this pluralist society, with multiple interests at stake, there needs to be widespread public participation -- in crucial decision-making, in risk assessment, in impact assessment, and in deciding what is ethical:

— because of the vast potential both for profit accumulation and for the concentration of power,
— because of the potential impact of altering all food crops and domesticates, and hence the entire global agriculture and food system, and ultimately the world economy and political system,
— because of the potential to impact and alter every ecological region and niche, by the introduction of genetically modified varieties with new resistances, new tolerances and extended habitats,
— because of the potential for the development of biological military products,
— because of the unimpressive record of the use of nuclear fission (this knowledge, when kept as restricted and privileged information, was primarily used to construct weapons of vast destructive capacity),
— because of the predictive regularity of massive industrial accidents such as Sarajevo, Bhopal, Chernobyl, etc. and the possibility of equally hazardous situations arising from genetic engineering techniques.

All new knowledge concerning RNA and DNA, and all new bioengineering techniques such as cloning, recombinant DNA, trans-specic hybrids and chimeras, etc., should not only belong in the public arena but there is an urgent need for public input into the ethical issues surrounding every aspect of genetic engineering, from as wide a spectrum of people with as diverse interests as possible.

Genetic engineering should not become exclusive property used to further enrich an elite corporate minority

Christian ethics regarding biotechnology

Christians call for:

An ethic of the biosphere as the subject and agent of divine creative and redeeming love.

A relational ethic: Life is more than the sum of the quarks and gluons, more than self-replicating assemblages of mechanical parts, it also includes evolving relationships that increase in capacity with evolving self-consciousness and self-awareness, and increase in power with increasing knowledge. This calls for responsibility and accountability for one's action to all other beings. Life is subjectivity in interrelationship with other subjects, and a mechanistic paradigm is totally inadequate.

An ethic based upon viewing the biosphere as a complex of organisms held together by interaction and interdependencies.

An inclusive ethic, that views people as within and dependent on nature.

A holistic and not a reductionist ethic.

An incarnational ethic, that stresses the immanence of God in the world, taking joy in the joy of all creatures, and suffering in the suffering of each. The pathos of God in a broken and suffering world is a constant Christian reflection.

A sacramental ethic, that views creation as holy, as divine creative self-expression. God gives life to all that is, to all species of life and all forms of matter.

A value ethic. The life of the world is not trash, is not a raw material input of consumer production, an element of wealth accumulation, to be discarded after use like surplus embryos or batches of clones withheld from the market for price regulation. Each and every being is of priceless value to itself and to God, in whom we all live and move and have our being.

A participatory ethic. Humility is the first step to moral maturity, and a certain humility is called for on the part of scientists and technologists to listen to the considered input of the entire public, and especially those most likely to be adversely affected by it, especially the Third World cultivators; to listen also to the artists, poets, conservationists, philosophers, clergy; to the voices of many who love the world and wonder at the magnificence, integrity and holiness of life.

SOME CONSUMER AND THIRD WORLD CONCERNS ON THE PATENTING OF BIOTECHNOLOGY PRODUCTS AND PROCESSES

Dr. Martin Abraham

Original: English

The advent of modern biotechnologies has further complicated the already controversial and hotly debated issue of property rights. The granting of industrial-type patents for biotechnology products and processes is projected to go far beyond any other existing system of property rights in fostering a stringent and stratified monopoly of patent protection -- much to the advantage of TNCs and industrialised countries, and to the disadvantage of consumers and Third World countries.

From past, present and emerging trends, the application of patents to biotechnology products and processes can be expected to precipitate a wide range of serious concerns.

Such consequences include:

— the possible devastation of subsistence or indigenous ventures, be it in the agricultural or any other sector;
— concentration of corporate power and control;
— marginalisation or elimination of small farmers;
— aggravation of genetic erosion;
— intensification of environmental degradation;
— creation of dependencies;
— inhibition of self-reliance;
— exacerbation of poverty and disempowerment among the masses;
— stifling of local initiatives for research and development;
— monopolisation of trade and prices;
— and greater polarisation between the haves and the have nots, particularly in Third World countries.

Considering pharmaceutical patents in Third World countries as a case in point, there are five possible scenarios, each with its own dynamics and differences. These have been tabulated below:

Example Country	Signatory to the Paris Convention	Nat. Patent Laws	Protection of Patents
Kenya	+	+	+
Brazil	+	+	—
Indonesia	+	—	—
Pakistan	—	+	+
Maldives	—	—	—

At the very heart of patent protection is the Paris Convention, adopted in 1883, and which has since then been revised six times. From a consumer and Third World perspective, it is disturbing that the Paris Convention does not have a preamble *per se* -- i.e. it neither contains any statement explicitly describing its goals and objectives, nor does it adequately stress the significance of the special interests and needs of consumers and Third World countries. Given the fact that industrialised and Third World countries are unequally matched in technological strength, expertise and resources, it is highly unlikely that the application of patents to biotechnology products and processes will in any way serve the interests or needs of consumers or Third World countries.

The Paris Convention is also biased in that patentees (usually a TNC or an industrialised country) are more inclined to transfer technologies that the patentees wish to transfer, rather than technologies that the recipients (mostly Third World countries) actually need or want. To compound the dilemma, even the terms of technology transfer are often solely dictated by the patentees, with little or no involvement of the recipients. The issue of technology transfer and its implications for patentees and recipients can also become the subject of prolonged stalemate and litigation -- a situation Third World countries can ill-afford in time or resources.

Each revision of the Paris Convention has extended the exclusive monopoly powers of patent holders

Just how unfair the Paris Convention is to consumers and Third World countries is well illustrated in the following extract from an UNCTAD report on The International Patent System: *Since its inception the Convention has grown haphazardly. Neither at the time of its adoption, nor during its six subsequent revisions, has the protection of specific interests of developing countries found any reflection in it. The Convention itself lacks structural homogeneity: differences in the types of members of the Convention and of its various Acts; differences in the types of industrial property dealt with; and differences in the possibility of accession to one or another set of its Articles.*

One of the commonly used indicators for determining the state of a country's industrial development is the degree of its self-reliance, meaning the strength of a country's local enterprises, and not the strength of foreign TNCs operating in the host country. From this standpoint, biotechnological patents are undoubtedly counter-productive to a Third World country's attempt to achieve self-reliance and industrial development. This is even more so, as the provisions of the Paris Convention are so heavily loaded in fa-

vour of TNCs and foreign patent holders, with scant or no attention being paid to the crucial concepts of public interest, people's needs, the obligations of the patentee, and the rights of the recipient country.

According to Surendra Patel, a former Director of the Technology Division of UNCTAD, there were some 3.5 million patents in the world by 1987. Of these, Third World countries had only 200,000. The nationals of Third World countries held only 30,000 of these patents -- i.e. less than one per cent of the world total. The other 170,000 -- or eight five per cent of the Third World total -- were held primarily by TNCs based in industrialised countries like the US, UK, FRG, France, Switzerland and Japan. To add insult to injury, less than five per cent of these patents were actually used for production purposes in Third World countries.

As Patel rightly points out, the patent system reserves Third World markets for foreigners. *It perpetuates perverse preferences (...) It is a system designed mainly for the benefit of foreigners, but legalised, operated and even subsidised by nationals.* This means that it is a system which guarantees private foreign gains at tremendous public cost to Third World countries.

Paradoxically, in the committy of nations -- as Patel puts it -- Third World countries account for seventy five per cent of global population, twenty per cent of global income, thirty per cent of global trade, and about forty per cent of global enrollment in higher education. But yet the Third World's share in the global patent system is not even one per cent. In the ultimate analysis, the present patent system can be said to represent the most unequal and most unjust of all relationships between industrialised and Third World countries.

It is a system which guarantees private foreign gains at tremendous public cost to Third World countries

It is therefore imperative that Third World integrity and solidarity be maintained and fortified in order to resist the proprietisation of biotechnology via patent protection monopolies. Third World countries must stand up and speak up with a concerted voice and say no to the patenting of biotechnology products and processes.

As a means to stimulate research and to safeguard the interests of inventors, including technological innovations developed indigenously in Third World countries, alternate measures may be employed. Such measures could include inventors certificates, user fees, sales taxes, fiscal incentives and other inventor reward mechanisms.

Needless to say, if Third World countries opt to adopt their own biotechnology patent laws, they will be wittingly or unwittingly establishing the last link in the vicious chain of privatisation in a process which will pave the way for TNCs to capture global market monopolies for their products and processes. In any case, Third World countries stand more to lose than gain if they were to join the rush to patent biotechnology products and processes.

Third World countries must stand up and say no to the patenting of biotechnology products and processes

In conclusion, I would like to highlight five points concerning patent protection and Third World countries, extracted and adapted from a paper by Kumariah Balasubramaniam, IOCU's Pharmaceutical Advisor:

1. Each revision of the Paris Convention, since its adoption in 1883, has extended the exclusive monopoly powers of patent holders and weakened the bargaining powers of Third World countries, which have to purchase technologies from TNCs who own the vast majority of the patents.

2. A critical evaluation of existing national and international patent systems reveals that they have had adverse effects on the economic, commercial and technological development of Third World countries.

3. Many aspects of patent legislation involve the relationship between patent owners and consumers. One of the principal functions of patent legislation, if any, should be to reconcile conflicting interests and to protect consumers and society.

4. Patent legislation provides incentives to private parties in the hope of assuring some benefits to society. All incentive policies have a social cost. Patent legislation is, thus, a compromise between benefits to certain parties like TNCs and benefits and costs to society. While the benefits to society are somewhat quantifiable, the costs are often not. This is one of the inherent flaws of existing patent legislation.

5. Being net importers of technology, Third World countries will have interests quite different from industrialised countries which are net exporters of technology. As such, Third World countries cannot simply replicate patent-related measures that have been or are being introduced in industrialised countries. Third World countries must learn from one another's experience, and formulate measures which are best suited to meet their own specific interests and needs.

PATENTING HUMAN MATERIAL: WHAT FORM OF POLITICAL RESPONSIBILITY?

Paula Bradish

Original: English

I feel that not only farmers, consumers, but also Parliamentarians and other Ministers -- people responsible for policy making in these areas -- do not in fact realise what is going on, what has been done in the past years in the area of patenting, and they certainly do not realise the implications. I say this after observing, for example, discussions in the German Parliamentarian commissions and hearings of different legal committees and so on in which it became obvious that Parliamentarians there suddenly realised that human genes were being patented, were being put into animals and so on. I also think that the discussion in the United States last fall about foetal tissue -- the use of foetal tissue in research and the commercialisation of foetal tissue -- also demonstrated this fact.

Speeding up or slowing down

This leads me to my first point: I think what we do not need is an instrument, a political instument which will further speed up technological innovation in this area, which will further speed up the transfer of scientific results to technological applications, and this is exactly what patenting is about. I think we need a slower-down and not a speeder-up. I think, further, that we must discuss the implications of patenting not just in the area of human application. We must look at them together with the impact of the research projects and their applications that are involved. We have to talk about both the medical risks and the social risks, and we have to talk about them in contrast to their actual benefits and their use value for society, all members of society, and this is of course also a question of allocation of resources in different areas, a point raised earlier by Dr. Hardon.

We have to compare for example the money being put into the genome project -- the project to sequence the entire human genome -- versus money being spent for real preventive medicine, for preventing certain diseases. We have to compare money used to create transgenic plants and animals, with money being spent just to identify some of the dozens of species, plant and animal species, which are being destroyed, which are disappearing daily in ecosystems all over the world. We have to think of the fact that patenting is actually a very powerful political instrument, a tool for directing scientific and technological progress, but one which is then not subject to public control. Because as became clear in the discussions in Germany, you cannot deny patents on the basis of their lack of benefit or any basis as a matter of fact other than the fact that they might be ethically objectionable or actually criminal.

From myth to reality

The EEC Directive, as far as I have understood it, has no clear provision on the use of patent law as applies to human cells, to human tissue, to DNA, to DNA probes. They are neither excluded nor otherwise clearly included. However, the are brought in via the definitions. For example the definition of a micro-organism is phrased in such a way that it includes all cells and apparently also human cells and human DNA. When we then hear that the European Commission states that the possible patenting of human beings is a myth, as happened this morning, then I consider this as throwing up a smoke screen to take away our attention from what is actually happening. Human genes, human cells, human tissue are being patented and this is going to increase in the near future. I feel that the potential impact of this is nearly as dramatic as actually making the final step to one day patenting human beings themselves.

Human genes, human cells, human tissue are being patented and this is going to increase in the near future

Some of this discussion took place on a broad level in the United States already two years ago. The fact that it took place in scientific journals, for the most part, has been one reason why it has not gotten into the public debate here, although at least in Germany the public debate on genetic engineering in general has been quite broad.

The first area is the patenting of human DNA, human DNA probes and sequences, and also processes used to sequence, map or analyse DNA. The second is the patenting of human cells, tissue or, also, processes used to manipulate them and products produced from such cells or tissues. And the third area I would like to mention is the area of medical procedures which are being developed or used, and here there have also been patent applications, in the area of human reproduction and human heredity. One example that I find very illustrative is the patent application for the embryo flushing procedure which was developed by the Seeds Brothers in Chicago a few years ago, where they applied for a patent both on the procedure itself and on some apparatuses used in this manipulation.

The human genome

There was an article published nearly two years ago entitled Who Owns the Human Genome?. It raised actually a number of the relevant questions which I would just like to report on here. The author asked, for example, can anyone actually own the human genome? Just as a matter of clarification the genome is the entirety of all human gene sequences. They asked, *If a company actually sequences a gene or a chromosome, does it have property rights, can it control use of this sequence?* Or to be even more specific, because in the meantime a company has been founded by the American biologist Walter Gilbert: if he does manage to sequence something, does he have the right to copyright or to patent the sequences that have been found by his new company and then decide who can use these sequences for further research or for medical application?

Some of the questions raised concern legal technicalities. For example, would a patent on human DNA meet the criterion of novelty, in other words is DNA more or less like a computer programme and once someone has written it down and formulated it, it is then an original piece of work? Another question raised was also what will be the effect of this on research? Will there be more secrecy, holding up the whole genome project, which now not only the US and Japan but also the EEC wants to get into? Will it stimulate innovation here or will it hamper progress in this area?

Paternity, criminality and human rights

Producing different kinds of DNA probes, one type the most important at the moment are the so-called restriction fragment length polymorphisms (RFLPs). These can be used on different levels for analysing human genes, be it in legal cases, in criminal laws for identifying possible suspects in criminal cases, in paternity cases, in looking for genetic disorders or genetic diseases, also in looking for so-called predispositions, that is gene sequences that are assumed today to be predisposing people to having people get later on in life cancer, diabetes, or other illnesses.

There are in fact patents already in this area, e.g. on the probes used in criminal cases and paternity cases in the UK, Federal Republic and other countries. One attorney working for a company in this area who already has about 600 different markers has said, *For 90% of the work we do, we do not see how we can share it.* That is, they feel that the work they are doing will have to be sold by the company to make it worthwhile for them to continue this research, including the probe that they have developed to diagnose cystic fibrosis prenatally or otherwise.

One of the other questions that have to be raised are whether this information does not violate very basic human rights in terms of intrinsically private information about the genetic make-up of persons, information that has to be collected if you are going to use these techniques and that many people feel -- and that is my feeling -- should not be used in databanks, should not be made available to be it the police, be it the immigration authorities and so on, in the way it is already being used today.

I think that there is a very high potential for discrimination using this genetic information on all levels of use, not only if it might one day be used by potentially totalitarian or racist governments. The recent election results in Berlin make this an even more real possibility and not only in Berlin but also in other European countries. I think we also have to ask what do we mean when we talk about the right to know. Is it not equally important to say that one has the right not to know and not to have this information even be collected?

I would vote for a moratorium on patenting in this area

Even more basic is the question whether or not the whole thrust of genetic research, in wanting to sequence the human genome, will lead to a new form of eugenics, a new form of selecting people on the basis of good and bad genes, and also of considering human life to be determined in the most important parts by the genetic make-up of people.

In the area of trade in and the use of human cells, tissues and organs, the development has gone farther already than most people actually know. There are more than 300 different patent applications in the United States for this area. Forty-nine percent of all U.S. medical institutions have applied for such patents, and one-third of the biotechnology companies in the United States use human cells and human tissues in some way.

Conclusion

I would like to point out three questions raised by the U.S. Office of Technology Assessment in its 1987 report on these issues, and answer them from my own viewpoint. First of all, is it in keeping with human dignity and respect for persons to allow human cells and tissues to be bought and sold and to be patented? I would say it is not. Secondly, are the possible benefits of this kind of use of cells and tissues outweighed by the risks? I feel the risks do indeed outweigh the benefits. Thirdly, will a market set up in the area of human tissues and human cells be equitable to all persons, including those who are financially disadvantaged, be it in the First or in the Third World? I feel very stongly, especially after what we have heard in recent months about world trade in human organs, that once again, those who are at the bottom end of the scale will be literally exploited (slaughtered, I think, is even the proper term at this point) for the benefit of those in more privileged parts of the world.

My final vote would be to reconsider these issues, to consider one basic human right to be a property right to one's own body or parts of one's body. At least, at the very least, I would vote for a moratorium on patenting in this area, simply because I feel that the majority of the world's population is nowhere near having reached a well-founded opinion on whether or not they want patenting not only of human tissues, human DNA, but of genes, plants animals and micro-organisms as well.

PATENTING LIFE? A POLITICAL QUESTION

Benedikt Härlin

Original: German

I would like to tell you how I, for the first time, realised that there was a conflict about patents. A friend of mine works in a company which manufactures extracts of camomile, making camomile products for baths, etc. A few years ago, this company was told by a much larger firm in Germany (which took them over) that they could not longer use this camomile to make the products which they had been making for years. This firm, Degusser, had actually managed to do this because it got a patent on one of the most important components of the camomile bath. Perhaps they had been doing this for a long time already but they came to the little company and said: well, we have patented this now.

The small company argued that this was impossible, that they had been making their camomile bath for years. But suddenly someone had registered a patent. The conflict is underway at the moment and as the large company obviously has a lot more money, it is probably going to be the one that wins out. What we might find in the long run is that neither of the companies is going to be able to work with camomile. I think that is sort of a parabole of what might be happening on the patent front in the future.

Why patents?

From the discussion we had here yesterday, I learned that first and foremost industry tells us genetic engineering can actually manufacture very useful products for society. There are certain doubts on this of course. I think personally that this is something which has not been discussed adequately. Then we hear that if industry does not get exclusive rights so that they can prevent people from manufacturing the same useful products, they will not to produce the products for us.

My question, as a politician, is why then at the moment so much money is being invested in genetic engineering without patent protection being available? My second question is what would happen if there were no patents. Mr. Duesing from Ciba-Geigy mentioned this yesterday. He said without patents, firms are going to have to keep a lot of information very secret and confidential within the company, and that this is a decisive political point in the conflict which we may have to fight out in the future.

In reality, however, I think that things are the other way around. When we look at current research programmes, we find that industry is investing a lot of money in R&D. In general, when biotechnology research programmes get subsidies from the EEC or other public funders, 50% of the initial outlay has to come from industry. So research programmes are only encouraged when there is cooperation between publicly funded universities and research institutes, and private enterprise. Society should carefully consider whether it is justified to invest money in a partner who might keep the results secret, when in fact they were funded by the public and belong to the public.

Why is so much money being invested in genetic engineering without patent protection being available?

We see that with the first patented animal, the Harvard mouse, the patent actually belongs to the DuPont company, who helped fund the research at Harvard. In the last 10 to 15 years, it has become ever clearer that through patent law, intellectual property becomes the property of companies rather than the property of scientists. In other words, the scientists do not actually get the rights to their own inventions. Companies come to scientists and say they will fund their research provided they get the patent out of it. So the question arises as to whether or not patent law in a certain way actually encourages industry vis-a-vis the scientific world, rather than being a way in which researchers can ensure that their products are justifiably recognised.

Nothing new?

At the moment, we are also facing the conflict as to whether the deliberate release of genetically modified organisms into the environment is justified. The European Community is drawing up a directive on this and a decisive argument put forward by industry is that when releasing these organisms, they are not doing anything that nature itself does not do. They claim that they are not doing anything new, that they are just doing it in a somewhat more quickly and more precise way.

With the discussion on patent law, the tone has changed completely. Here we are suddenly dealing with totally new inventions. It is a question of whether one can register ownership rights to these. So it is not just an ethical issue, as to whether patenting of life forms should be allowed, but it is also a question of deciding whether or not these inventions are actually so novel.

The time schedule

The Commission's proposal has been referred to the Legal Committee of the European Parliament. Mr. Rothley from

the Social Democrats is to submit the report on that. I am the rapporteur of the Research Committee on this matter. The formal timetable we have on paper at the moment is that the Committee on Legal Affairs has to have approved its report on this Directive on the 17th of April. In my experience I must say that this is probably not going to happen and as we know this Parliament draws to an end in June, there is going to be a new Parliament coming in. This current one will probably not deal with this Directive any further. Thus far we have had rather confusing information on the whole business and I think we need a lot more time to consider in detail what we feel is allowable in this sector.

Yesterday we heard from several people that the Commission has not taken full account of the breeders, the consumers and the farmers when drafting this Directive. On the other hand we have heard industry say that they have not been consulted adequately in the preparation of this Directive either. So I think that involving all interested sectors, whether in politics or in society as a whole, should be something which Parliament ensures will occur.

My group is unfortunately the group which had to organise the first discussions on this. I believe that it is more the duty of the Commission and the European Parliament to do so. I do hope that the Commission is actually going to organise discussions on this matter and the Parliament should certainly work on this further. It is important to realise that the decision on whether or not this Directive is to be approved, or how it is to be approved, is not something which the Parliament can decide upon. Parliament does not have the legislative power to ensure that its position is implemented.

We need a lot more time to consider in detail what we feel is allowable in this sector

I think that what is going to be decisive in the next six months is the question of how at the national level this patent law is going to be discussed. It is no use just carrying out debates here and learning more and more about the whole question. We heard yesterday that in farming circles there has hardly been any discussion on this at all. I think it is an important question that should perhaps be brought up in the electoral campaigns for the elections to the next European Parliament. This would ensure that the individual parties -- not only those that make up the European Parliament -- but also the different parties in the national governments should ensure that this question plays an important role the election campaign.

The U.S.A. is ahead

Finally I would like to point out that a critical question in this whole discussion is how the U.S. is going to approach things. This is the regular argument which never fails to come up. Industry says: They are already doing all this in the U.S. and if we do not do the same they will carry on and Europe will lose out in the competition. I would like to point out that in the last American Congress, a number of bills were discussed and one of these concerned a moratorium on the patenting of life forms, including plants and micro-orgnaisms. However , the moratorium was not passed and instead, a draft law was approved in Congress (not in the Senate) which bases itself on the idea of authorising patent law but providing quite extensive waiver rules for farmers. I would like to quote a comment on this from the Industrial Biotechnology Association, which groups together all the biotechnology companies in the U.S.A. This remark was published in their annual report and points to something which is going to be very important in Europe as well:

The industry intended to split the pro-moratorium coalition by pitting the farmers against the other coalition members and it was intended to be politically popular for the Wisconsin Congressmen in election year. With the suport of the farmers, we succeeded in defeating the Republican Rose's moratorium bill in sub-committe by a vote of 9-6 and 21-22.

It is clear that the American Biotechnology Industrial Association says that because of this exemption for farmers -- and this is something which is going to be discussed with the EEC Directive as well -- they have succeeded in defeating the coalition which had been formed in the United States against the patenting of life forms. The coalition tried to get a moratorium bill passed, industry managed to split them, and with the help of the farmers who found the proposed waivers an acceptable deal, they managed to get the question of patenting through.

The U.S. Senate has not approved the draft law yet, so the new Congress is going to have to deal with this issue once more. It is very important for us to develop a common strategy in both Europe and the United States. I think that is the conclusion we can draw from our discussions here.

Society should carefully consider whether it is justified to invest money in a partner who might keep the results secret

A moratorium

I think we should propose a moratorium on such patents in order to ensure that we have time to think things out properly and start considering alternatives to patenting. This should also guarantee that the public is kept properly informed about what is happening and what decisions have to be taken -- it should not just be a few Commission and Council members that are informed about this.

PATENTING LIFE FORMS: THE DEBATE IN ITALY

Fabio Terragni

Original: Italian

A couple of words by way of introduction on my group, GAB. We are about a year old. Our aim is to promote and stimulate debate in Italy on the question of genetic engineering. We are working to promote public involvement in decision-making in the research field.

People have not felt that patents were a hot issue in Italy. People keeping tabs on biotechnology in Italy in the 1980s spent a lot of time concentrating on the U.S. They were particularly interested in the Chakrabarty case. It was very prominent as you know. For the first time it raised certain themes which of course are still of prime importance today. The debate therefore, from the Italian viewpoint, has been primarily an American one. We in Italy have been looking at things from a bit of a distance.

Until very few years ago, we have always viewed this in a somewhat detached way and we have not been politically or emotionally involved in the subject. Things changed with the American Patent Office's judgement in April of 1987, when it declared animals patentable. The echo in the Italian press was considerable. The idea of patenting animals is of course rather new and this had quite an effect on public opinion. Things hit the headlines and especially the Catholic church became very concerned about it. An authoritative group of Catholic philosophers published a document which came out against patenting animals on ethical grounds. In the period between April and December 1988, newspapers published a large number of articles. There was a general feeling of uneasiness in the country and journalists were concerned with the question of patenting life forms. People did not know quite how they felt, but they felt uneasy, if I may put it that way.

Maybe we are not very good at doing our homework in general in Italy

The Italian press has not been as interested in the EEC Directive on patenting as they were on the patented mycomouse. To date, no journalist has considered this Directive as being any kind of a scoop that would be worth splashing all over the headlines. But things are changing in Italy. People are beginning to pay attention to this. Certain NGOs involved in international cooperation are very interested in the effects this will have on the future of their work. Other political groups are beginning to have their attention aroused.

A parliamentarian seminar

A few weeks ago, a working party was set up in the National Federation of Green Lists to concentrate on the key issues in biotechnology. Certain initiatives have been decided upon. On the 14th of March (1989), there will be a parliamentarian seminar in Rome. Here, two EEC Directives, the one on patenting and the one on deliberate release, will be discussed. Also bovine growth hormone and ethical problems concerned with genome sequencing and other aspects of human embryo research will be on the agenda.

This meeting is meant to stimulate a broader discussion on the implications of biotechnology and to pressure the government to act on it. We will discuss with Italian MPs about the implications and we will be trying to lobby politicians in general, government politicians in particular. A lot of them have not done their homework, perhaps that is an Italian problem. Maybe we are not very good at doing our homework in general in Italy.

Also an information campaign on all of these subjects will start. We will produce flyers, brochures and get them spread around. We are distributing the European leporellos as well and they will be sparking off a general information campaign.

Signatures against patenting

Yet another initiative was launched. It is an idea to collect signatures. We are intending to go into a referendum campaign next spring against the use of pesticides in farming. This is a hot issue in Italy because of, for example, the pollution of water. There has been quite a debate running between environmentalists and industry. The general attitude of industry if they are told they are polluting the countryside, they say, *biotechnology will help us when it comes.* So we are trying to discuss with industry about the negative sides of biotechnology and among these we see the question of patenting higher life forms and deliberate release.

To be effective we need a certain number of signatures in Italy to get a referendum in motion. We are convinced that we will be able to get 300,000 to 400,000 signatures to show our government and Europe what the people's position is in Italy. We think a referendum can be an important opportunity to involve public opinion and get a campaign going. I have a proposal which we might want to think about: might it not be a good idea to gather throughout Europe, say, a million signatures against patenting higher life forms?

A seminar in Massa Carrara

We also plan to organise a seminar on the use of agricultural biotechnologies in Massa Carrara, a village in Tuscany. In this village there is a very large plant of Montedison, one of the biggest chemical companies in Italy. Last July there was an accident in that plant and in a local referendum in Massa Carrara, 80% of the people voted for closing the plant. Monetedison stopped pesticide production, following order from the mayor of Massa Carrara, but then switched its operations to agrobiotechnology. This has raised even more concern among the population. In this context we want to organize the seminar in Massa Carrara. It will demonstrate to the outside world that local pressure is important and that it can be an effective tool for change. What is also important with the seminar is to keep the dialogue going between people who are working in science and technology.

I realize that I am talking about the Italian situation, but many of my points are valid for Europe as a whole. In the environmentalist movement in Italy we still have a lot to learn from the experience of our brothers and sisters abroad, particularly in northern Europe. But we already have got a few trophies. Our success against nuclear energy, for example, is something I think we can chalk up to our credit and this may indicate that we may have hopes of more success in the future.

What about the instruments we intend to use? We want to make information available, we want to promote a well-informed debate among the general population. We are aware of the fact that most people in the population are prepared to come out against patenting of higher life forms. I think it is important to explain to the people back home about what is happening here in Brussels. Many different groups in the population have not been involved and consulted before this draft Directive went to press. That is a good argument we have in our favour. The issue is too important, and decisions should be based on a broad public discussion.

We must also concentrate on making scientific information available to the general public, not only in the framework of this Directive but in general. The general public should be well-informed so that they can play a critical role in policy-making.

Science for the many

We should all be thinking about which principles we are going to adopt when promoting science. We have to think about the very meaning of science -- what is the point of scientific discoveries unless they are put to good use? If science serves only a few, then surely it is not worth the effort. Science should serve the many. We think the problem with patenting higher life forms is that it is something which is useful only to the few and we are opposed to it.

A major problem with biotechnology and other branches of science at the moment is that certain scientists become the slaves of industry and some of them are not feeling happy about the direction their work is taking them in. This means we have to rethink the role of scientists in society. People might say we want to put a straightjacket on science. Maybe they are right! There has not been much of a a straightjacket on science and if there was, it has been the industry that has been lacing it.

If we want to be successful we have to make sure that public opinion can influence policy decisions. The main aim in the whole world, not just Europe, should be to put science at the service of society as a whole. We should not just be going for big bucks.

I feel we have to block this Directive and I think we need to improve the feedback and information flow between science and society. If we look at life forms as systemic naturalists and not as biotechnologists we will be aware that the feedback, the interplay in nature is important to get equilibrium, homeostasis between North, South, man and the environment. We are all living in a world of balance -- we have got to preserve the balance. Patenting higher life forms risks, I believe, upsetting this balance. We've got to put the brakes on this Directive.

If science serves only a few, then surely it is not worth the effort

A final point. This is perhaps turning to people who might accuse us of being irrational. I think we have to call into question the so-called notion of rationality because rationality has always been just what some people call the paradigm of control, the productive logic only. We should not only be productive -- we should be reasonable. We have to think more about the longer term consequences, the effects of a particular action; we have to think more of what is good and bad for man and the environment in all the decisions we take. We should not be anti-scientific or obscurantist. Science should not be viewed as a cold subject, detached from the population. We should have an intensive and responsible science for the future.

PATENTING OF LIVING ORGANISMS IN DENMARK?

Jesper Toft

Original: English

Introduction

The Nordic situation on the question of patenting is very diverse. Only Sweden is party to the European Patent Convention (EPC) (Denmark, Norway and Finland are not) and only Denmark and Sweden have ratified the UPOV Convention. In Norway there is a ban on patenting any living organism, including microbes *per se*. Genetically engineered microbes can be patented in the other Nordic countries.

The Nordic countries have set up an Expert Group on Biotechnological Inventions and Intellectual Property Law which recently came up with a final report. The Expert Group found that:

— ethics should be dealt with outside the scope of intellectual property law;
— the impact on national food supply is a non-problem;
— there was no agreement in the Group as to whether the patent system was well suited for protection of living organisms.

The Expert Group proposed to keep farmers outside the effects of industrial property rights on plants when applied in practice (farmers' privilege), and recommended that the socio-economic impact of biotechnology on society should be dealt with (the Expert Group did not cover this). The Group also recommended that no step to patent animals should be taken for the moment and that it is better to regulate by other means than by a ban on patenting animals. Sweden, for instance, has a proposal for a regulation to make it possible to ban engineering on animals for animal welfare reasons.

The situation in Denmark

As mentioned above, Denmark has ratified the UPOV Convention but not the European Patent Convention, which is also the case with two other EEC memberstates, Ireland and Portugal. Until now there have been five attempts to get Denmark to be a member of the EPC, but without success. The reason is that the Danish Parliament is recognising this issue to be a question of sovereignty, which means that joining the EPC requires a majority of five-sixths in the Parliament.

In January, the Danish Government made a new proposal to join the EPC. The situation is not clear whether there will be the necessary majority behind it: now only four to six more votes against it will be enough to stop the proposal, and we are lobbying for that.

But why stop the proposal? There are many reasons. The first one is a formal one. A former Danish Government has agreed that if Denmark joins the EPC, the EEC Patent Directive will be automatically ratified. Many Danish Parliamentarians are against that kind of harmonisation -- and they do not believe that this question will also be decided in the Danish Parliament with a five-sixths majority. The EEC Council of Ministers may use its power and just ratify!

On the other hand, rumours in Denmark tell me that the EEC Commission will change its attitude and set up a motion so that the EEC Directive will only apply for 10 memberstates -- Portugal will sign the EPC very soon, leaving Ireland and Denmark outside.

If Denmark joins the EPC, the EEC Patent Directive will be automatically ratified

Other reasons to be critical against joining the EPC are of ethical and environmental character. We have pushed the Danish Parliament to take a political decision as to whether plants and animals should be patentable, because it is a political decision and should not be taken by lawyers or by courts. Being able to patent plants and animals will stimulate companies to do research in these fields and the question is whether that is wanted. This, again, is a political question and the decision should be taken by politicians. That did not happen in the U.S.A. in 1980, when the Supreme Court made its famous decision to patent microbes. The reason to do so was that as the law was set up, it gave no reason to ban a patent on a living organism. The responsible answer from politicians should have been to change the law. That did not happen in the U.S.A., as we all know.

Patenting and biotechnology

Now to quite another thing. As a biologist, I would like to look at the different definitions set up by lawyers as to why and how living things can be patented. The reason is that they are quite out of step with biology!

What is a microbe? There is, from a biologist's viewpoint, no clear definition, but lawyers have decided that in patent law, a microbe is defined, among others, as plasmids and non-differentiated plant and animal cells. A biologist would never dream of calling a plasmid or non-differentiated plant cell a microbe! The reason why lawyers define it as such is that you can regenerate a whole

plant from such a cell -- which, again, is the reason why the plant is patentable.

What about genes? Genes also seem to be patentable. But genes already exist in nature and are not new! Only the technique to isolate the genes is new -- not the gene itself. No patent therefore should be allowed on a gene.

What about plants? Plants are not inventions as they occur naturally and are maybe discoveries. Plant varieties are based on material already known. It is not possible to produce a new variety with biotechnology alone. Breeding will also be involved. It is not possible today to totally describe the plant variety or the breeding process. No patents on plants.

It is much better to pass a law suited for biology than to adapt biology to existing laws

What about essentially biological processes? Lawyers say that it depends on the extent of human intervention; biologists would say that a process is biological if it changes the heredity of the plant or animal. Lawyers won again -- as you know, it is now possible to patent a plant and an animal if it is created by a microbiological process.

But no one, in their wildest fantasies, could imagine that plants and animals could be created by microbiological processes when the European Patent Convention was developed nearly 20 years ago. But lawyers can do all these things without knowledge of the fundamentals of biology. It is only a question of definition and who is responsible for these and for what purpose. The conclusion is that patent lawyers have adapted biology to patent law, in spite of the fact that it is contrary to biological laws and definitions. Reason: pressure from industry.

It is, to my best opinion, against the spirit of patent law to grant such patents. For three reasons:

First, there is no guarantee on the result (mutation and so on makes results unstable). That is the *legal* point.

The second point is *ethical.* Living things are part of our heritage. Plants and animals have a certain sovereignty over and above, for example, a machine. The same world view you can find in some animal rights legislation and the world view of the old farmers. Ethical considerations have consequently been a contributing cause when prohibiting the patenting of living organisms. The patent system was born at a time when the world view was mechanistic.

The third point is the *political* one. Patents give exclusive rights to a monopoly. The right to freely use genetic material in breeding talks in its own way against any patent. And one thing more: the socio-economic impact on society of extensive patenting can only be a guess, as we lack any analysis or assessment of that issue.

It is urgent to introduce a moratorium on all patents on plants and animals

Recommendations

Consequently it is evident that the patent law is not suited for living organisms. If patenting is wanted in this specific field it will be necessary to pass a new law, which can consider the public interests much better than the patent law. It is much better to pass a law suited for biology than to adapt biology to existing laws.

For these reasons it is urgent to introduce a moratorium on all patents on plants and animals, and to use this period to start a thorough analysis and assessment of the problems. This could be a good basis for public debate.

ANNEX 1

Council Directive
of .....
on the legal protection of biotechnological inventions
(../.../EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community and in particular Article 100A thereof,

Having regard to the proposal from the Commission,

In co-operation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas differences exist in the legal protection of biotechnological inventions offered by the laws and practices of the Member States and such differences could create barriers to trade and to the creation and proper functioning of the internal market;

Whereas such differences in legal protection could well become greater as Member States adopt new and different legislation and administrative practices or as national jurisprudence interpreting such legislation and practices develops differently;

Whereas biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries and the protection of biotechnological inventions can be considered of fundamental importance for the Community's industrial development;

Whereas the patent system must adapt to new technological developments which may involve living matter but which also fulfil the requirements for patentability;

Whereas no prohibition or exclusion exists in national or international patent laws which preclude the patentability of living matter as such;

Whereas national patent systems have in the past successfully adapted to technical developments and scientific breakthroughs in according patent protection to such developments where appropriate;

Whereas the investments required in Research and Development particularly for recouping that investment can only be effectively guaranteed through adequate legal protection;

Whereas without effective and approximated protection throughout the Member States of the Community, such investments might well never be made;

Whereas some inventions developed through biotechnology and genetic engineering are at present not clearly protected in all Member States by existing legislation, administrative practice, and court jurisprudence; and such protection, where it exists, is not the same or has different attributes;

Whereas the uncoordinated development in the Community of the legal protection for biotechnological inventions in the Member States could result in the creation of new disincentives to trade to the detriment of further industrial development in such inventions and of the completion of the internal market;

Whereas existing differences having such effects need to be removed and new ones having a negative impact on the functioning of the common market and the development of trade in biotechnological goods and services prevented from arising;

Whereas international developments in the field of legal protection of the results of biotechnology and genetic engineering demonstrate the advantages to be gained from approximation of national legislation;

Whereas scientific and technological developments are often a result of international collaboration on research and, in consequence, need exists to ensure that biotechnological inventions may benefit from comparable protection on an international level;

Whereas international instruments exist or are under consideration to harmonise various aspects of the legal protection of biotechnological inventions, they are not sufficient for Community purposes which must take account of the needs of Community science and industry and a Community market;

Whereas the patent laws applicable at present in the Member States contain disparities which hinder the development of trade in biotechnological goods and services, distort competition within the common market and therefore directly affect the establishment and functioning of that market; whereas it is particularly important to remove these disparities because at the stage reached at present in establishing the common market, there would appear to be an urgent need to ensure that undertakings will be offered the possibility of obtaining effective and equivalent legal protection in all Member States for the results of their research activities in any part of the Community;

Whereas an approximation of the legislation of the Member States is also necessitated by existing language in national laws originating in certain international patent and plant variety conventions which have given rise to considerable uncertainty as to the possibility of protecting biotechnological inventions concerning plant matter and microbiological inventions, language such as the exclusion from patentability of plant and animal varieties and of essentially biological processes for the production of plants and animals;

Whereas it is necessary to encourage potential innovation in the full range of human endeavors by recognising that human intervention which consists of more than the selection of biological material and allowing such material to perform inherently biological functions under natural conditions should be considered patentable subject matter and should not be regarded essentially biological;

Whereas it is seemly that the legislation of the Member States should be harmonised in such a way so as not to conflict with the existing international conventions on which many Member States' patent and plant variety laws are based;

Whereas the Community's legal framework on the protection of biotechnological inventions can be limited to laying down certain principles as they apply to the patentability of living matter as such; to the ability to use a deposit mechanism in lieu of written descriptions to satisfy the enabling disclosure requirements for patent application procedures; to a reversal of the burden of proof where release of self-replicable matter has occurred and to the right to a non-exclusive dependency license for plant and animal varieties;

Whereas, in view of the fact that the function of a patent is to reward the inventor with an exclusive but time bound right for his creative efforts and thereby encourage inventive activities, the right-holder should be entitled to prohibit the use of patented self-

replicable material in situations analagous to those where it would be permitted to prohibit such use of patented, non-self-replicable products, i.e. in respect of the production of the patented product itself;

Whereas, in the area of agricultural exploitation of new plant characteristics resulting from genetic engineering, guaranteed remunerated access in the form of licenses of right must be provided for as an exception to the general principles of patent law,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER 1

Patentability of Living Matter

Article 1

Member States shall ensure that their national patent laws comply with the provisions of this Directive.

Article 2

A subject matter of an invention shall not be considered unpatentable for the reason only that it is composed of living matter.

Article 3

1. Micro-organisms, biological classifications other than plant or animal varieties as well as parts of plant and animal varieties other than propagating material thereof of the kind patentable under plant variety protection law shall be considered patentable subject matter. Claims for classifications higher than varieties shall not be affected by any rights granted in respect of plant and animal varieties.

2. Notwithstanding the provisions of paragraph 1, plants and plant material shall be considered patentable subject matter unless such material is produced by the non-patentable use of a previously known biotechnological process.

Article 4

Uses of plant or animal varieties and processes for the production thereof shall be considered patentable subject matter.

Article 5

Microbiological processes shall be considered patentable subject matter. For purposes of this Directive, this term shall be taken to mean and to include a process (or processes) carried out with the use of or performed upon or resulting in a micro-organism.

Article 6

A process consisting of a succession of steps shall be regarded a microbiological process, if the essence of the invention is incorporated in one or more microbiological steps of the process.

Article 7

A process in which human intervention consists in more than selecting an available biological material and letting it perform an inherent biological function under natural conditions shall be considered patentable subject matter.

Article 8

A subject matter of an invention, including a mixture, which formed an unseparated part of a pre-existing material, shall not be considered unpatentable for the reason only that it formed part of said natural material.

Article 9

A subject matter of an invention, including a mixture, which formed an unseparated part of a pre-existing material, shall not be considered as an unpatentable discovery or as lacking novelty for the reason only that it formed part of said natural material.

CHAPTER 2

Scope of Protection

Article 10

The use of a product protected by a patent comprising or consisting of genetic information to develop another such product or the use of a patented process to obtain such a product shall not be regarded experimental for purposes of establishing patent infringement, if the developed product obtained from the experiments or its progeny in identical or differentiated form, is used for other than private or experimental purposes.

Article 11

If a product enjoying patent protection and put on the market by the patentee or with his consent is self-replicable, the rights conferred by the national patent shall not extend to acts of multiplication and propagation only where such acts are unavoidable for commercial uses other than multiplication and propagation.

Article 12

1. If the subject matter of an patent is a process for the production of living matter or other matter containing genetic information permitting its multiplication in identical or differentiated form, the rights conferred by the patent shall not only extend to the product initially obtained by the patented process but also the identical or differentiated products of the first or subsequent generations obtained therefrom, said products being deemed also directly obtained by the patented process.

2. Any extension of the protection conferred by the patent to a process as indicated under paragraph 1 to a product obtained thereby shall not be affected by any exclusion of plant or animal varieties from patentability.

Article 13

The protection for a product consisting of or containing particular genetic information as an essential characteristic of the invention shall extend to any products in which said genetic information has been incorporated and is of essential importance for its industrial applicability or utility.

CHAPTER 3

Dependency License for Plant Varieties

Article 14

1. If the holder of a plant breeders' right or a variety certificate can exploit or exercise his exclusive rights only by infringement of the rights attached to a prior national patent, a non-exclusive license of right shall be accorded to the breeders' right holder to the extent necessary for the exploitation of such breeders' right where the variety protected represents significant technical progress, upon payment of reasonable royalties having regard to the nature of the patented invention and consistent with giving the proprietor of such patent due reward for the investment leading to and developing the invention.

2. A license under paragraph 1 shall not be available prior to the expiration of three years from the date of the grant of the patent or four years from the date on which the application for a patent was filed, whichever period last expires.

3. If a license according to paragraph 1 has been granted, and if a variety protected by a plant breeders' right or variety certificate can be exploited by the patentee only by infringement of the rights attached to such a variety, a non-exclusive license shall be accorded to the original patentee to the extent necessary for the exploitation of the breeders' right or variety certificate, upon payment of reasonable royalties having regard to the nature of the improvement and consistent with giving the proprietor of the breeders' right due reward for the investment leading to and developing the new variety.

4. Where disagreements arise with regard to the significance of the technical progress and as to the level of royalties, Member States shall provide for a court of competent jurisdiction to resolve the dispute.

CHAPTER 4

Deposit, Access and Re-Deposit

Article 15

1. If an invention involves the use of a micro-organism or other self-replicable matter which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, or if it concerns such matter per se, the invention shall only be regarded as being disclosed for purposes of national patent law if:

(a) the micro-organism or other self-replicable matter has been deposited with a recognised depository institution not later than the date of filing of the application;

(b) the application as filed gives relevant information as is available to the applicant on the characteristics of the micro-organism or other self-replicable matter;

(c) the depository institution and the file number of the deposit are stated in the application.

2. The information referred to in paragraph 1(c) may be submitted:

(a) within a period of sixteen months after the date of filing of the application or, if priority is claimed, after the priority date;

(b) up to the date of submission of a request for early publication of the application;

(c) within one month after the national patent office has communicated to the applicant that a right to inspection of the files exists pursuant to paragraph 3(a)(ii) below.

The ruling period shall be the one which is the first to expire. The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to the deposited matter being made available to the public in accordance with this Article.

3.a) Unless the application has been refused or withdrawn or is deemed to be withdrawn, the deposited matter shall be available upon request:

(i) to any person from the date of publication of the patent application, and

(ii) to any person having a right to inspect files under the provisions of national patent law relating to applications under which rights are invoked against such a party, prior to the date of publication;

b) Subject to the provisions of paragraph 4, such availability shall be effected by the issue of a sample of the deposited matter to the person making the request (hereinafter referred to as the requester). Said issue shall be made only if the requestor has undertaken vis-à-vis the applicant for or proprietor of the patent:

(i) not to make the deposited matter or any matter derived therefrom available to any third party;

(ii) to use the deposited matter or any matter derived therefrom in any country only for experimental purposes concerning the invention, with the proviso that this restriction will cease, in the country of the patent right on the basis of which the sample of the deposited matter was obtained, with the grant of a patent or other enforceable right in the invention involved. This provision shall not apply in the country of the patent right on the basis of which the sample of the deposited matter was obtained insofar as the requester is using the matter under a compulsory license. The term compulsory license shall be construed as including ex officio licenses and the right to use patented inventions in the public interest.

4. Until the date on which the technical preparations for publication of the application are deemed to have been completed, the applicant may inform the national patent office that, until the publication of the mention of the grant of the patent, the availability referred to in paragraph 3 shall be effected only by the issue of a sample to an expert nominated by the requester.

5. The following may be nominated as an expert:

(a) any natural person provided that the requester furnishes evidence, when filing the request, that the nomination has the approval of the applicant;

(b) any natural person recognised as an expert by the national patent office. The nomination shall be accompanied by an undertaking from the expert vis-à-vis the applicant; paragraphs 3(b)(i) and (ii) shall apply, the requester being regarded as a third party.

6. For the purposes of paragraph 3(b), any matter derived from the deposited matter shall be deemed to be any matter derived the-

retrom by culturing or in any other way of replication which matter still exhibits those characteristics of the deposited matter which are essential to or for carrying out the invention. The undertaking referred to in paragraph 3(b) shall not impede a deposit of derived matter, necessary for the purposes of patent protection.

7. The request provided for in paragraph 3 shall be submitted to the national patent office on a form recognised by that office. The national patent office shall certify on the form that a national patent application referring to the deposit of the micro-organism or other self-replicable matter has been filed, and that the requester or the expert nominated by him is entitled to the issue of a sample of the micro-organism or other self-replicable matter.

8. The national patent office shall transmit a copy of the request, with the certification provided for in paragraph 7 to the depository institution as well as to the applicant for, or the proprietor of, the patent.

9. Member States shall designate recognised depository institutions for the purposes of this Article.

10. If a micro-organism or other self-replicable material has been deposited in accordance with paragraphs 1 and 2 and has become available to any person or an expert in accordance with paragraphs 3 or 4, it shall henceforth be regarded available to the public in accordance with paragraph 1.

Article 16

1. If a micro-organism or other self-replicable matter deposited in accordance with Article 15 ceases to be available from the institution with which it was deposited because:

(a) the micro-organism or other self-replicable matter is no longer viable, or

(b) for any other reason the depository institution is unable to supply samples,

and if the micro-organism or other self-replicable matter has not been transferred to another depository institution recognised for the purposes of Article 15, from which it continues to be available, an interruption in availability shall be deemed to have occurred if a new deposit of the micro-organism or other self-replicable matter originally deposited is made within a period of three months from the date on which the depositor was notified of the interruption by the depository institution and if a copy of the receipt of the deposit issued by the institution is forwarded to the national patent office within four months from the date of the new deposit stating the number of the application or of the national patent.

2. In the case provided for in paragraph 1(a), the new deposit shall be made with the depository institution with which the original deposit was made; in the cases provided for in paragraph 1(b), it may be made with another depository institution recognised for the purposes of Article 15(9).

3. Where the institution with which the original deposit was made ceases to be recognised for the purposes of the application of Article 15, whether entirely or for the kind of micro-organism or other self-replicable matter to which the deposited micro-organism or other self-replicable matter belongs, or where that institution discontinues, temporarily or definitively, the performance of its functions as regards deposited micro-organisms or other self-replicable matter, and the notification referred to in paragraph 1 from the depository is not received within six months from the date of such an event, the three-month period referred to in paragraph 1 shall begin on the date on which this event is announced in the official publication of the national patent office.

4. Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited micro-organism or other self-replicable matter is the same as that originally deposited.

5. If the new deposit provided for in the present Article has been made under the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure of 28 April 1977, the provisions of that Treaty shall prevail in case of conflict.

6. If a deposit is not accepted or if the deposited material is no longer available from the depository institution and a re-deposit according to paragraphs (1) through (5) does not or could not remedy the unavailability, such unavailability shall not affect the patentability of the invention if the applicant/patentee provides the requesting party entitled to receive a sample with such sample certifying its identity with the material used in the invention or obtained as the invention or with the originally deposited material, as the case may be.

7. If a patent is deemed invalid because the patentee can no longer provide for a sample of the deposited material in accordance with this Article, such invalidity shall in no case have retroactive effects.

CHAPTER 5

Reversal of the Burden of Proof

Article 17

1. If the subject matter of a patent is a process for obtaining a new or known product, the same product when produced by any other party shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process, if a necessary means to carry out the process had been deposited in accordance with Article 14 and had been released to a third party.

2. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.

CHAPTER 6

Miscellaneous

Article 18

Any exclusion from patentability or from the field of industrial applicability of surgical or diagnostic methods practised on an animal body shall apply to such methods only if practised for a therapeutic purpose.

Article 19

For the purposes of this Directive:

(a) the word micro-organism, where used, shall be interpreted in its broadest sense as including all microbiological entities capable of replication, e.g. as comprising, inter alia, bacteria, fungi, viruses, mycoplasmae, rickettsiae, algae, protozoa, and cells; and

(b) the words self-replicating matter, where used, shall be interpreted to comprise also matter possessing the genetic material necessary to direct its own replication via a host organism or in any

other indirect way, e.g. as comprising, inter alia, seeds, plasmids, DNA sequences, protoplasts, replicons and tissue cultures.

Article 20

1. Member States shall bring into force the laws necessary to comply with this Directive not later than 31 December 1990.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

Article 21

This Directive is addressed to the Member States.

Done at Brussels, ... 198 .

For the Council

The President

ANNEX 2

European Patent Convention
Articles 52 and 53

Article 52

Patentable Inventions

(1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:

(a) discoveries, scientific theories and mathematical methods;

(b) aesthetic creations;

(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;

(d) presentations of information.

(3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Article 53

Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to ordre public or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

ANNEX 3

PATENTING LIFE FORMS IN EUROPE SEMINAR STATEMENT

In the aftermath of the ICDA/GRAEL International Conference on Patenting Life Forms in Europe (European Parliament, 7-8 February 1989) attended by representatives of the European Commission, the biotechnology industry and plant breeders, farmers' organisations, etc. over 60 people from some 50 NGOs in 14 countries met at the Seminar for Social Interest Groups on the patenting of life forms. In order to stimulate wider public debate on the vast implications of patenting life in Europe, the following statement was adopted in plenary at the closing of the Seminar.

In October 1988, the Commission of the European Communities published a proposed Directive on the Legal Protection of Biotechnological Inventions. Following this proposal, all EEC memberstates are to adapt national legislation by 1991 in order to make life patentable. Earlier legal decisions in EEC countries already led to an extension of patent laws to living beings. The participants of the seminar are deeply concerned about the mounting pressure to make life patentable and thus subject to private property.

OUR CONCERNS

1. Biotechnology, as it is being developed now, takes life merely as a set of chemical substances and molecules that happen to be able to reproduce and are only meant to function as productive machinery. The extension of intellectual property rights to living beings reflects the brokenness between humans and the rest of nature. In particular the patenting of animals, and the lack of specific exclusion of the patenting of (parts of) human beings in the Commission's Directive, is in complete violation with the European Patent Convention which forbids the patenting of inventions that are contrary to morality.

2. Today, knowledge and technological ability are power. The patenting of life will further concentrate the new, vast power of biotechnology in the hands of a few transnational corporations. It will effectively move research on this new technology further away from public institutions and thus from public influence over whether and how it should be developed. It will further extend corporate control over agriculture and food production, and industrialise farming in the sense that agriculture becomes merely a supply system for industrial raw materials. Also, safety and ecological considerations regarding the release of engineered organisms into the environment will increasingly be exposed to intensified economic pressure if the patenting of life is permitted. Patenting life will also promote the rapidly growing commercialisation of human genes, cells and tissues and thus contribute to exploitative and eugenic trends in medicine.

3. Genetic resources are the essential basis of the new biotechnologies. Genetic diversity largely originates from what is now the Third World. It is the farmers who have -- for millennia and free of charge -- conserved, nurtured and developed this tremendous wealth, particulary in developing countries. Allowing for the patenting of genetic materials would completely deny this role and further destroy indigenous agricultural practices that currently form the base of the conservation of biological diversity at the local level. Additionally, it would further undermine the principle of free exchange of genetic resources on which world food security is based, and frustrate international efforts to conserve these precious resources.

Apart from the above concerns, we feel that any decision on the patenting of life forms should be based on a broad public discussion and on intense consultations with public interest groups. The indiscriminate promotion of all forms of so-called technological progress has already resulted in profound ecological and socio-economic problems. We must therefore reconsider the use of current monopoly patent laws, especially in the field of biotechnology, and promote alternative, *non-exclusive* ways of stimulating technical and scientific development.

OUR PROPOSALS AND COMMITMENTS

1. We urge the EEC Commission to withdraw its current proposed Directive on the patenting of life and start a broad public discussion and consultation at the international level on the implications of the patenting of life forms.

2. We urge the European Parliament to reject the current proposed Directive, and demand from the Commission a proposal which takes the above mentioned concerns fully into account.

3. We ask our governments to start a public discussion at the national level on the patenting of life, and initiate a consultation process with all concerned public interest groups.

4. We demand that any decision on the patenting of life be based on considerations of economic, social, political and ethical implications, and that indepth studies be carried out to assess and promote alternative ways to stimulate and adjust technical and scientific development.

5. We accept a major role in the development of public discussion and policy related to biotechnology and the patenting of life. We therefore commit ourselves to carry our concerns back to the NGOs and networks with which we are engaged and start a broad campaign against the patenting of life at the local, national and international levels.

ANNEX 4:
CONFERENCE PROGRAMME

TUESDAY 7 FEBRUARY

PUBLIC FORUM ON THE IMPACT OF PATENTING LIFE FORMS

SESSION I: 9:30 - 11:15

Patenting Life Forms: Context, Scope and Consequences.

Speakers:

Dr. R. Stephen Crespi
Patent Consultant (UK)

Mrs. Sandra Keegan
Commission of the European Communities (EUR)
DG-III: Internal Market and Industrial Affairs

Mr. Dieter Obst
Commission of the European Communities (EUR)
DG-VI: Agriculture

Ms. Marie-Angèle Hermitte
Centre National pour la Recherche Scientifique (F)

Session II: 11:15 - 13:00

The Impact of Patenting on Biotechnology Research and Industry in Europe.

Speakers:

Mr. Pierre-Benoît Joly
Institut National de la Recherche Agronomique (F)

Mr. John Ducsing
Ciba-Geigy Ltd. (CH)

Dr. G. J. Boonman
Zelder BV (NL)

Mr. Pat Roy Mooney
Rural Advancement Fund International (Canada)

Session III: 15:00 - 16:45

The Impact of Patenting Life Forms on Agriculture.

Speakers:

Dr. J.J. Hardon
Centre for Genetic Resources (NL)

Ms. Françoise Comte
Comité des Organisations Professionnelles Agricoles, Comité Général de la Coopération Agricole (EUR)

Mr. Gérard Choplin
Coordination Paysanne Européenne (EUR)

Mr. Jean-Pierre Chiaradia-Bousquet
United Nations Food and Agriculture Organisation (UN)

Session IV: 16:45 - 18:30

The Voice of the Public Interest Groups That Will be Affected By Patenting Life in Europe.

Speakers:

Ms. Joyce DaSilva
Compassion in World Farming (UK)

Rev. Dr. Freda Rajotte
World Council of Churches (CH)

Dr. Martin Abraham
International Organisation of Consumers Unions (Malaysia)

Ms. Paula Bradish
FINNRAGE (FRG)

WEDNESDAY 8 FEBRUARY

SEMINAR FOR PUBLIC INTEREST GROUPS: ALTERNATIVES AND ACTION

Morning Session: 9:30 - 11:00

The Political Debate Building Up Around Patenting Life Forms in Europe.

Speakers:

Mr. Benedikt Härlin
Member of European Parliament, GRAEL (FRG)

Mr. Eisso Woltjer
Member of European Parliament, Socialist Group (Pv/dA, NL)

Mr. Jesper Toft
NOAH (DK)

Mr. Fabio Tarragni
Gruppo di Attenzione sulle Biotechnologie (I)

PRESS CONFERENCE: 11:00 - 12:00

Afternoon Session
(only for NGOs)

Working Groups by Region: 14:00 - 16:00
The European Campaign on Patenting Life Forms in Europe

Final Plenary: 16:00 - 18:00
Towards Establishing a Common NGO Position on Patenting Life Forms in Europe

ANNEX 5

Participants List: Overview by Country

Name:	Organisation:	Country:
		AUSTRIA
Ms. Ebba Sinzinger		
Mr. Harald Wosihnoj	GeN-A	
Ms. Susanne Fromwald	GeN-A	
Mr. Sepp Strauss	GeN-A	
		BELGIUM
Ms. Maria Arapakis		
Mr. Gareth Davies		
Mr. Danny Smagghe	AGALEV	
Mr. Alex Danau	Collectif Stratégies Aliment.	
Mr. Deleu	COPA/COGECA de la CE	
Mr. Hofkens	COPA/COGECA de la CE	
Ms. Francoise Comte	COPA/COGECA de la CE	
Ms. Karola Taschner	EEB	
Mr. Coppieters	EECOD	
Mr. Ian Fergusen	Eurogroup for Animal Welfare	
Mr. Anton Gazenbeek	Eurogroup for Animal Welfare	
Ms. Sandra Keegan	European Commission (DG-III)	
Mr. Dieter Obst	European Commission (DG-VI)	
Ms. Joanna Tachmintzis	European Commission (DG-XI)	
Ms. Mantegazzini	European Commission (DG-XI)	
Mr. Andrew McIlroy	European Parliament	
Ms. Joannah Summlan	European Parliament	
Mr. Hannes Lorenzen	European Parliament	
Ms. Patricia Paye	European Parliament	
Ms. Katarina Labaere	European Research Associates	
Mr. Ducatelle	EWONL	
Mr. Marc Pallemaerts	Greenpeace Belgium	
Ms. Topsy Jewell	Greenpeace International	
Ms. Sue Milner	Greenpeace International	
Mr. René de Schutter	GRESEA	
Mr. Simon Stocker	ICDA	
Prof. Alain Gérard	IEE/ULB	
Mr. Louis Van Eylen	Ministère de l'Agriculture	
Mr. Hermann Diricks	Ministère de l'Agriculture	
Mr. Gilbert Houins	Ministère de l'Agriculture	
Mr. W. Van Ormelingen	Ministère de l'Agriculture	
Mr. Rudy de Meyer	NCOS	
Ms. Sunneva Saetevik	Norwegian Ministry of Environ.	
Mr. Roger Dubois	PAN-B	
Mr. A. Motquin	PAN-B	
Mr. Bert Lokhorst	PAN-Europe	
Ms. Anne-Marie Bouckaert	Plant Genetic Systems	
Ms. Zoe White	Quaker Counc. for Eur. Affairs	
Mr. Jeff Swimmer	Reuters	
Mr. G. Jansen	Stichting Technologie Vlaand.	
Mr. Marcel Poppe	Vita-Vitalis V2W	
Mr. Tony Long	WWF-International	
Ms. Lucette Flandroy	'Biofutur'	
Ms. Deborah Mackenzie	'New Scientist'	
Mr. Pat Roy Mooney	RAFI	CANADA
Mr. George Brock-Nannestad	A/S De Dansk Sukkerfabrikker	DENMARK
Mr. Steffan Dahllof	Freelance Kontoret	
Mr. Jesper Toft	NOAH	
Mr. Eric Jullien	CERNA - Ecole des Mines	FRANCE
Ms. Marie-Angèle Hermitte	CNRS	
Mr. Gérard Choplin	CPE	
Mr. Pierre Coers	Elsevier/Biofutur	
Ms. Christine Detourbet	Essor Europe	
Mr. Pierre-Benoît Joly	INRA-IREP	

Name:	Organisation:	Country:
Mr. Stéphane Boucharenc	SOLAGRAL	
Mr. Bertrand Codron	SOLAGRAL	
Mr. Nicolas Marin	Université de Paris	
Ms. Silvia di Natale		F.R. GERMANY
Ms. Petra Huge	ABL/Neuland	
Ms. Eva Lindenmaier	AL-Berlin	
Ms. Birthe E. Jessen	Bildungszentrum Gohrde	
Mr. Jost Ettlin	BUKO-Agro-Koordination	
Dr. Kay Beese	Fed. Ministry of Agriculture	
Ms. Paula Bradish	FINRRAGE	
Mr. Benedikt Härlin	Gen-ethic Network	
Mr. Dan Leskien	Gen-ethic Network	
Mr. Egbert Nitsch	GRAEL	
Mr. F.W. Graefe zu Baringdorf	GRAEL	
Mr. Paolo Sala	Lega Per L'Ambiente	
Ms. Elisabeth Van der Graaf	Max-Planck Institute	
Dr. Rainer Mulang	Max-Planck Institute	
Mr. Andreas Höing	SAN-BRD	
Mr. Michael Flitner	SAN-BRD	
Ms. Crescentia Freudling	SAN/PAN-BRD	
Mr. Albrecht Müller	Wissenschaftsladen Tübingen	
Mr. Ernesto Benelli	Centro Internaz. Crocevia	ITALY
Mr. Antonio Onorati	Centro Internaz. Crocevia	
Mr. J.P. Chiaradia-Bousquet	FAO	
Mr. Fabio Terragni	GAB	
Mr. Henny Helmich	SID	
Mr. Eddy Brand	STOA Project	LUXEMBOURG
Dr. Martin Abraham	IOCU	MALAYSIA
Ms. Cecilie Willock	NIEO Network	NORWAY
Ms. Audgunn Oltedal	NRK	
Ms. Inger Naess	Royal Ministry of Environment	
Ms. Pia Soerensen	Royal Ministry of Environment	
Ms. Bjorg Storesund	Royal Ministry of Industry	
Mr. Hermod Haug	SAN-N	
Ms. Kristin Rosendal	The Fridtjof Nansen Institute	
Fura Zygmunt	Polish Ecological Club	POLAND
Mr. Pedro Lopez de Munain	EHNE	SPAIN
Ms. Renée Vellvé	ICDA Seeds Campaign	
Mr. Henk Hobbelink	ICDA Seeds Campaign	
Mr. Emilio Quintana	Universidad Autonoma Barcelona	
Mr. Ola Jonsson	CUF	SWEDEN
Mr. Olle Nordberg	Dag Hammarskjöld Foundation	
Mr. Thomas Senac	SAN-S	
Ms. Danielle Ecoffey	CASIN	SWITZERLAND
Dr. Bernhard Roth	Ciba-Geigy Ltd.	
Mr. John Duesing	Ciba-Geigy Ltd.	
Mr. Gerard Vuffray	CPE - UPS	
Ms. Maria-Alicia Ruibal	IUED	
Mr. Walter Smolders	Sandoz	
Mr. Miges Baumann	SAN-CH / Id3W	
Mr. Antoine F. Goetschel	Schweizer Tierschutz (STS)	
Mr. Claude Beck	UEPA	
Dr. Mark M. Rissi	UEPA	
Dr. Freda Rajotte	World Council of Churches	
Ms. Nienke Brouwer	Alternative Consumers' Assoc.	THE NETHERLANDS
Ms. Margje Vlasueld	Alternative Consumers' Assoc.	
Dr. Jaap Hardon	Centre for Genetic Resources	
Mr. P. Mars	GIST-Brocades	
Mr. Herman Verbeek	GRAEL	

Name:	Organisation:	Country:
Mr. Diepman	KLB	
Mr. Frank Bos	Kontact Groep Biotechnologie	
Mr. Huib de Vriend	Kontact Groep Biotechnologie	
Mr. Piet Schenkelaas	Kontact Groep Biotechnologie	
Mr. Vincent Lucassen	Kontakt Groep Biotechnologie	
Mr. Tim Verhoef	Kritisch Landbouwberaad	
Mr. Johann de Groote	Kritisch Landbouwberaad	
Drs. S.S. De Vries	Landbouwschap	
Mr. G. Heerink	LTB	
Ms. Phili Viehoff	Member European Parliament	
Mr. J.C.H. Perizonius	Netherlands Patent Office	
Mr. Ferry Rijnbout	NOVIB	
Ms. Frieda Bos	Opraappers Agricul. Communica.	
Mr. Jan Hogenboom	Twente University	
Mr. Nico Verhagen	University of Wageningen	
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